

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

ESTELLE GELLER

Plaintiff,

v.

WYETH

Defendant.

CIVIL ACTION

NO. 02-4718

**APPENDIX OF UNPUBLISHED OPINIONS
CITED IN WYETH'S MEMORANDUM IN SUPPORT OF
MOTION TO DISMISS THE COMPLAINT**

Of Counsel:
JOHN W. VARDAMAN
F. LANE HEARD III
WILLIAMS & CONNOLLY
725 W. TWELFTH STREET, N.W.
Washington, DC 20005-5901
(202) 434-5000

MICHAEL T. SCOTT
ROBERT A. NICHOLAS
JOAN A. YUE
REED SMITH LLP
2500 One Liberty Place
1650 Market Street
Philadelphia, PA 19103-7301
(215) 851-8100

Attorneys for DEFENDANT **WYETH**

DATED: August 14, 2002

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TAB 1

LEXSEE 2000 U.S. Dist. LEXIS 16963

LAWRENCE D. BERNHARDT, Plaintiff, vs. PFIZER, INC., Defendant. ARNOLD LIEBMAN, Plaintiff, vs. PFIZER, INC., Defendant.

00 Civ. 4042 (LMM), 00 Civ. 4379 (LMM)

UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK

2000 U.S. Dist. LEXIS 16963

November 16, 2000, Decided

November 22, 2000, Filed

DISPOSITION:

[*1] Defendant's motion granted.

facturer's drug was within the specialized experience and expertise of the appropriate federal administrative agency, and referral of the issue to the agency was more appropriate than the exercise of the court's jurisdiction.

CASE SUMMARY

PROCEDURAL POSTURE: Defendant moved for judgment on the pleadings with regard to the request of plaintiffs, in consolidated product liability actions, for injunctive relief requiring defendant manufacturer of a drug to notify users and physicians of the results of a study concerning the effectiveness of the drug.

OVERVIEW: Plaintiffs brought product liability actions against defendant manufacturer of a hypertension medication, and sought, inter alia, to require defendant to notify users of the medication and their physicians of the results of a study which found defendant's medication to be less effective than another medication in preventing heart failure. The court declined to exercise its jurisdiction since whether the notice was warranted was a decision within the relevant regulatory scheme and informed expert discretion of the federal Food and Drug Administration. Plaintiffs' request for a notice involved neither a purely legal question nor a question that could be decided without specialized knowledge and expertise. No unwarranted delay would result from referral of the issue to the administrative agency since plaintiffs' product liability claims were not dependent upon issuance of the requested notice by the court and could proceed to adjudication.

OUTCOME: Motion was granted; whether notices were required concerning the effectiveness of defendant manu-

CORE CONCEPTS

Civil Procedure : Justiciability : Ripeness

Under the doctrine of primary jurisdiction, a district court may refer a matter within its original jurisdiction to the appropriate administrative agency if doing so will promote proper relationships between the courts and administrative agencies charged with particular regulatory duties.

Civil Procedure : Justiciability : Ripeness

The doctrine of primary jurisdiction allows a federal court to refer a matter extending beyond the conventional experiences of judges or falling within the realm of administrative discretion to an administrative agency with more specialized experience, expertise, and insight. Specifically, courts apply primary jurisdiction to cases involving technical and intricate questions of fact and policy that Congress has assigned to a specific agency.

Civil Procedure : Justiciability : Ripeness

Although no fixed formula governs the application of the doctrine of primary jurisdiction, the court identifies four factors to consider: (1) whether the question at issue is within the conventional experience of judges or whether it involves technical or policy considerations within the agency's particular field of expertise; (2) whether the question at issue is particularly within the agency's discretion; (3) whether there exists a substantial danger of inconsistent rulings; and (4) whether a prior application to the agency has been made.

Civil Procedure : Justiciability : Ripeness

The court must balance the advantages of applying the doctrine of primary jurisdiction against any potential costs

and delays resulting from the referral of the matter to the administrative agency. If a court finds that an administrative agency has primary jurisdiction over the claim, the court stays the matter and directs plaintiff to file a complaint with the agency.

Civil Procedure : Justiciability : Ripeness

Referral of an issue to an administrative agency on the grounds of primary jurisdiction is inappropriate when the issue in question is a purely legal one or turns on a factual matter requiring no technical or policy expertise.

Governments : Agriculture & Food : Federal Food, Drug & Cosmetic Act

Congress has granted the Food and Drug Administration (FDA) the authority to ensure that drugs are safe and effective. The FDA approves the labeling of a drug as part of the new drug approval process. 21 U.S.C.S. § 355(b); 21 C.F.R. § 201.100(c)(2). Such labeling is broadly defined and includes "Dear Doctor" and "Dear Patient" notices. The FDA has the authority to either alert users of a drug and their physicians if it determines that the drug creates an imminent danger to health or gross deception of the consumer, 21 U.S.C.S. § 375(b), or to request the drug manufacturer to revise the labeling for the drug. 21 U.S.C.S. § 393. Finally, plaintiffs have the ability to request the FDA to take either action pursuant to a citizen petition provision. 21 C.F.R. § 10.30.

COUNSEL:

For LAWRENCE D. BERNHARDT, plaintiff (00-CV-4042): Steven G. Schulman, Milberg, Weiss, Bershad, Hynes & Lerach, Salvatore J. Graziano, Milberg, Weiss, Bershad, Hynes & Lerach L.L.P., New York, NY.

For ARNOLD LIEBMAN, plaintiff (00-CV-4379): Steven G. Schulman, Milberg, Weiss, Bershad, Hynes & Lerach, Salvatore J. Graziano, Milberg, Weiss, Bershad, Hynes & Lerach L.L.P., New York, NY.

For ARNOLD LIEBMAN, plaintiff (00-CV-4379): Kenneth G. Gilman, Gilman and Pastor, Edward L. Manchur, Esq., David Pastor, Douglas M. Brooks, Gilman and Pastor, L.L.P., Boston, MA.

For ARNOLD LIEBMAN, consolidated plaintiff (00-CV-4042): Douglas M. Brooks, Gilman & Pastor, L.L.P., Boston, MA.

For PFIZER, INC., defendant (00-CV-4042): David Klingsberg, Kaye, Scholer, Fierman, Hays & Handler, New York, NY USA.

For PFIZER, INC., defendant (00-CV-4379): Lori B. Leskin, Kaye, Scholer, Fierman, Hays & Handler, L.L.P., New York, NY.

For DOROTHY HOLZER, intervenor-plaintiff (00-CV-

4042): Steven G. Schulman, Milberg, Weiss, Bershad, Hynes & Lerach, L.L.P., New York, NY.

JUDGES:

LAWRENCE M. McKENNA, U.S.D.J..

OPINIONBY:

LAWRENCE M. McKENNA

OPINION:

MEMORANDUM AND ORDER

McKENNA, D.J.

Lawrence D. Bernhardt and Arnold Liebman ("plaintiffs") have filed product liability actions n1 against Pfizer, Inc. ("defendant") for claims arising out of their use of Cardura, a prescription drug manufactured by defendant. Presently before this Court is defendant's motion for judgment on the pleadings pursuant to Fed. R. Civ. P. 12(c) with respect to plaintiffs' claim for mandatory injunctive relief in the form of an emergency notice sent to Cardura users and their physicians. For the reasons set forth below, the Court finds that the Food and Drug Administration ("FDA") has primary jurisdiction and stays the present motion until the FDA decides the plaintiffs' request for a notice.

n1 The Court consolidated these actions by Order dated June 21, 2000.

Background

Pfizer manufactures and markets the antihypertensive drug doxazosin under the brand name "Cardura" for the [*2] treatment of hypertension. (Pls. Compl. P1.) n2 In 1994, the National Heart, Lung and Blood Institute ("NHLBI"), a division of the National Institute of Health ("NIH"), began an eight-year study called Antihypertensive and Lipid Lowering Treatment to Prevent Heart Attack Trial ("ALLHAT") which included in its scope the comparison of doxazosin to chlorthalidone in the treatment of hypertension. (Id. P23.) On March 8, 2000 the NHLBI issued a press release announcing that it was discontinuing this part of the ALLHAT study because doxazosin "was found less effective than [chlorthalidone] in reducing some forms of cardiovascular disease." (NIH News Release dated Mar. 8, 2000, Leskin Aff. Ex. B.) Plaintiffs claim that the ALLHAT findings demonstrate that "Cardura users are twice as likely to be hospitalized for congestive heart failure and have a significantly higher chance of suffering from certain serious cardiac events, including strokes, as compared with patients" who took chlorthalidone to treat hypertension. (Pls. Mem. Opp'n at 1.) Plaintiffs seek an order requiring Pfizer to send

a notice to Cardura users and their physicians regarding the ALLHAT findings with respect to Cardura. [*3] The proposed notice to physicians would state, among other things, that a study by NHLBI "has demonstrated that Cardura (doxazosin) is less effective in preventing heart failure compared to a widely used diuretic drug, chlorthalidone." (Pl. Ex. 1), and the proposed notice to patients, among other things, the same. (Pl. Ex. 2.)

n2 Citations herein to "Pls. Compl." are to the complaint filed in *Bernhardt v. Pfizer*, 00 Civ. 4042.

Discussion

Defendant and the United States n3 between them argue that plaintiffs' request for injunctive relief should be denied because plaintiffs lack standing to seek such relief (defendant), the FDA has primary jurisdiction to determine whether the ALLHAT findings warrant the issuance of notices to Cardura users and their physicians (defendant and the United States) and the relief plaintiffs seek is preempted by the Food, Drug and Cosmetics Act ("FDCA"), 21 U.S.C. § 301 et seq. (United States.) Because the Court finds that the FDA has primary jurisdiction, [*4] it is unnecessary to discuss defendant's other arguments.

n3 At the Court's request, the United States has submitted a Statement of Interest which is limited to plaintiffs' request that the Court order defendant to notify Cardura users and physicians of the ALLHAT study findings.

Under the doctrine of primary jurisdiction, a district court may refer a matter within its original jurisdiction to the appropriate administrative agency if doing so will "promote proper relationships between the courts and administrative agencies charged with particular regulatory duties." *Nader v. Allegheny Airlines, Inc.*, 426 U.S. 290, 303, 48 L. Ed. 2d 643, 96 S. Ct. 1978 (1976). As the Second Circuit has explained,

the doctrine of primary jurisdiction allows a federal court to refer a matter extending beyond the 'conventional experiences of judges' or 'falling within the realm of administrative discretion' to an administrative agency with more specialized experience, expertise, and insight. Specifically, courts [*5] apply primary jurisdiction to cases involving technical and intricate questions of fact and policy that Congress has assigned to a specific agency.

National Communications Assoc. v. American Telephone & Telegraph Co., 46 F.3d 220, 222-23 (2d Cir. 1995) (citations omitted). Although no "fixed formula" governs the application of the doctrine, *United States v. Western*

Pacific R.R., Co., 352 U.S. 59, 64, 1 L. Ed. 2d 126, 77 S. Ct. 161 (1956), the Second Circuit has identified four factors to consider:

(1) whether the question at issue is within the conventional experience of judges or whether it involves technical or policy considerations within the agency's particular field of expertise;

(2) whether the question at issue is particularly within the agency's discretion;

(3) whether there exists a substantial danger of inconsistent rulings; and

(4) whether a prior application to the agency has been made.

National Communication Ass'n., 46 F.3d at 222. The Court also must balance the advantages of applying the doctrine against any potential costs and delays resulting from the referral of the matter to the agency. [*6] See id. If a court finds that an administrative agency has primary jurisdiction over the claim, the court stays the matter and directs plaintiff to file a complaint with the agency. See *Reiter v. Cooper*, 507 U.S. 258, 268-69, 122 L. Ed. 2d 604, 113 S. Ct. 1213 (1993).

Referral of an issue to an agency on the grounds of primary jurisdiction is inappropriate when the issue in question is a purely legal one, see *Board of Educ. v. Harris*, 622 F.2d 599, 607 (2d Cir. 1979), or turns on a factual matter requiring no technical or policy expertise. See *National Communication Ass'n.*, 46 F.3d at 223. Here, whether the ALLHAT findings constitute sufficient grounds to justify plaintiffs' request for a notice is neither a purely legal question nor a question that can be decided without specialized knowledge and expertise. Plaintiffs are not arguing that the ALLHAT findings trigger a statutory or regulatory notification requirement or that Pfizer's inaction violates the FDCA. n4 Rather, plaintiffs ask this Court to determine, on the basis of presumably scientific and medical principles to be developed at an adversary preliminary injunction hearing, [*7] that the ALLHAT findings warrant a notice to all Cardura users and their physicians. The FDA, not this Court, has the relevant expertise. See *Henley v. Food and Drug Admin.*, 77 F.3d 616, 621 (2d Cir. 1996) ("The average consumer cannot be expected to analyze and weigh each conflicting study. ... The FDA possesses the requisite know-how to conduct such analyses, by sifting through the scientific evidence to determine the most accurate and up-to-date information regarding a particular drug."); *Premo Pharm. Labs., Inc. v. United States*, 629 F.2d 795, 803 (2d Cir. 1980) ("The FDA ..., as distinguished from a court, possesses superior expertise, usually of a complex scientific nature.").

n4 Indeed, plaintiffs cannot make those arguments because there is no private right of action to enforce the provisions of the FDCA. See *PDK Labs, Inc. v. Friedlander*, 103 F.3d 1105, 1113 (2d Cir. 1997) (citing 21 U.S.C. § 337(a)).

Congress has granted the [*8] FDA the authority to ensure that drugs are safe and effective. See *Premo Pharm. Lab.*, 629 F.2d at 804. The FDA approves the labeling of a drug as part of the new drug approval process. See 21 U.S.C. § 355(b); 21 C.F.R. § 201.100(c)(2). Such labeling is "broadly defined" and has been found to include the "Dear Doctor" and "Dear Patient" notices requested by plaintiffs. See *Walls v. Armour Pharm. Co.*, 832 F. Supp. 1467, 1482-83 (M.D. Fla. 1993); see also *Kordel v. United States*, 335 U.S. 345, 349-50, 93 L. Ed. 52, 69 S. Ct. 106 (1948) (holding that literature sent separately by drug manufacturer supplementing or explaining materials accompanying the drug, constitutes "labeling" under FDCA). The FDA also has the authority to either alert Cardura users and their physicians if it determines that Cardura creates "an imminent danger to health or gross deception of the consumer," § 375(b), or to request Pfizer to revise the labeling for Cardura. See § 393. Finally, plaintiffs have the ability to request the FDA to take either action pursuant to a "citizen petition" provision. 21 C.F.R. § 10.30. The above [*9] review of the relevant regulatory scheme convinces this Court that whether the notice requested by plaintiffs is warranted is a decision that has been squarely placed within the FDA's informed expert discretion.

Because there is no law for the Court to apply, there is no opportunity for inconsistent interpretations of law. There is, however, a substantial danger of a much more

serious inconsistency. An order by this Court directing Pfizer to issue the notices would not preclude the FDA from either issuing a second notice or requiring Pfizer to do so, thus creating the potential for inconsistent directions concerning a serious medical ailment and how it is best treated.

Finally, the Court finds that plaintiffs' failure to make a prior application to the FDA for the issuance of the notices is not dispositive and that no substantial delay will result from the application of the primary jurisdiction doctrine in this case. Plaintiffs' claims for product liability are not dependent on whether the notices are issued by this Court and the remainder, and indeed, the substance, of plaintiffs' lawsuit may continue in this Court.

Conclusion

The Court grants defendant's motion for judgment [*10] on the pleadings pursuant to Fed. R. Civ. P. 12(c) as to plaintiffs' claim for injunctive relief in the form of notice and plaintiffs shall direct that request for injunctive relief to the FDA for review. The Court hereby stays such part of plaintiffs' case until a determination is made by the FDA. n5

n5 The preliminary injunction hearing scheduled for November 20, 2000 is canceled as moot.

SO ORDERED.

DATED: November 16, 2000

New York, New York

LAWRENCE M. McKENNA

U.S.D.J.

TAB 2

1 of 1 DOCUMENT

**DEAN EDGAR and NANCY EDGAR, Plaintiffs, v. DANEK MEDICAL, INC., a
Tennessee corporation, Defendant.**

CASE NUMBER: 96-2451-Civ-T-24A

**UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF FLORIDA,
TAMPA DIVISION**

1999 U.S. Dist. LEXIS 6431; CCH Prod. Liab. Rep. P15,668

March 31, 1999, Decided

DISPOSITION:

[*1] Plaintiffs' Motion to Extend Time to File Response to Defendant's Motion for Final Summary Judgment (Doc. No. 29, filed February 1, 1999) GRANTED; Defendant's Motion to Extend Time to File Reply Memorandum in Further Support of its Motion for Summary Judgment (Doc. No. 36, filed March 17, 1999) GRANTED; Defendant's Motion for Summary Judgment (Doc. No. 22, filed August 6, 1998) GRANTED; Plaintiffs' Motion to Reinstate Fraud on the FDA claim (Doc. No. 31, filed February 24, 1999) DENIED. Judgment entered in favor of the defendant, DANEK MEDICAL INC.

CASE SUMMARY

PROCEDURAL POSTURE: Defendant medical manufacturer moved for summary judgment in plaintiff patient and wife's products liability suit alleging negligence, strict liability, breach of implied warranty, fraud, and breach of consortium. Plaintiffs also moved to "reinstate" a claim that defendant perpetrated fraud on the Food and Drug Administration.

OVERVIEW: The court granted defendant medical manufacturer's motion for summary judgment in plaintiffs' products liability suit alleging negligence, strict liability, breach of implied warranty, fraud, and breach of consortium. Plaintiffs were also denied leave to amend their complaint to include a claim of fraud on the Food and Drug Administration (FDA). Plaintiffs contended that defendant encouraged surgeons to utilize defendant's "bone screws" in ways not approved by the FDA and that plaintiffs were injured by a surgeon's unapproved use of the screws in plaintiff patient's back. First, plaintiffs failed to generate a genuine issue of material fact as to the defective manufacture or design of the hardware given

the generality of their expert's opinions. Thus, summary judgment was proper on plaintiffs' negligence and strict liability claims. Second, plaintiff patient's surgeon was a learned intermediary insulating defendant from liability for fraud/failure to warn. Finally, it would be futile to allow plaintiffs leave to amend their complaint because, under Florida law, plaintiffs could not state a claim for fraud on a third party such as the FDA.

OUTCOME: The court granted defendant medical manufacturer's motion for summary judgment in plaintiffs' products liability suit alleging negligence, strict liability, breach of implied warranty, fraud, and breach of consortium in part because plaintiffs failed to generate a genuine issue of material fact as to the defective manufacture or design of defendant's hardware. Plaintiffs were also denied leave to amend their complaint.

CORE CONCEPTS

Civil Procedure : Summary Judgment : Summary Judgment Standard

Summary judgment is proper if the pleadings, depositions, answers to interrogatories, and admissions on file, together with affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to summary judgment as a matter of law.

Torts : Products Liability : Negligence

The elements of a negligence claim are: (1) the existence of a duty toward plaintiff; (2) a breach of that duty; and (3) injury to plaintiff actually and proximately caused by that breach. In addition, where the claim for negligence arises in context of product liability, plaintiff must also show some defect in the product, whether of manufacture or design.

Evidence : Witnesses : Expert Testimony

Evidence : Witnesses : Opinion on Ultimate Issue

Causation opinion based solely on a temporal relationship is insufficient to satisfy the requirements of Fed. R. Evid. 702.

Torts : Products Liability : Strict Liability

In order to hold a manufacturer liable on the theory of strict liability in tort, the user must establish the manufacturer's relationship to the product in question, the defect and unreasonably dangerous condition of the product, and the existence of the proximate causal connection between such condition and the user's injuries or damages.

Torts : Products Liability : Breach of Warranty

There can be no claim for breach of implied warranty in the absence of privity. Plaintiff who purchases a product, but does not buy it directly from defendant, is not in privity with that defendant.

Torts : Products Liability : Duty to Warn

Torts : Products Liability : Misrepresentation

In order to recover for a medical manufacturer's failure to warn where its alleged misrepresentations were made to plaintiff's doctor and not to plaintiff patient directly, plaintiff must prove that the manufacturer's failure to warn the physician was the proximate cause of the injuries to plaintiff. In other words, plaintiff must show that the physician would not have used the device in question if he or she had been warned by the manufacturer of its risks. A physician's independent awareness of those risks thus disrupts probable cause and obviates any liability for a manufacturer's failure to warn.

Civil Procedure : Pleading & Practice : Pleadings : Amended Pleadings

In situations in which a responsive pleading has been served, Fed. R. Civ. P. 15(a) provides that a party may amend its pleading by written consent of the adverse party or by leave of the court. Nonetheless, it is well settled that there is no obligation to allow amendment if to do so would be futile. An amendment is futile if the cause of action asserted therein could not withstand a motion to dismiss. That is, a court may deny leave to amend when it appears beyond doubt that the proponent can prove no set of facts to support the proposed amendment.

Torts : Products Liability : Misrepresentation

Under Florida law, an actionable fraudulent misrepresentation is: (1) a false statement of fact; (2) known by defendant to be false at the time that it was made; (3) made for the purpose of inducing plaintiff to act in reliance thereon; (4) action by plaintiff in reliance on the correctness of the representation; and (5) resulting damage or injury to plaintiff.

COUNSEL:

For DEAN EDGAR, NANCY EDGAR, plaintiffs: Robert

Paul Chadwick, Anzalone & Chadwick, P.A., Tampa, FL.

For DANEK MEDICAL, INC., defendant: Edward W. Gerecke, Carlton, Fields, Ward, Emmanuel, Smith & Cutler, P.A., Tampa, FL USA.

For DANEK MEDICAL, INC., defendant: Stephen S. Phillips, Pepper, Hamilton & Scheetz, Philadelphia, PA USA.

JUDGES:

SUSAN C. BUCKLEW, United States District Judge.

OPINIONBY:

SUSAN C. BUCKLEW

OPINION:

ORDER

This cause comes before the Court on Defendant's Motion for Summary Judgment (Doc. No. 22, filed August 6, 1998), Plaintiffs' Motion to Extend Time to File Response to Defendant's Motion for Final Summary [*2] Judgment (Doc. No. 29, filed February 1, 1999), Plaintiffs' Motion to Reinstate Fraud on the FDA claim (Doc. No. 31, filed February 24, 1999), and Defendant's Motion to Extend Time to File Reply Memorandum in Further Support of its Motion for Summary Judgment (Doc. No. 36, filed March 17, 1999). Plaintiff filed an in camera response in opposition to Defendant's Motion for Summary Judgment on March 8, 1999. n1 Defendant has filed a response in opposition to Plaintiff's Reinstate Fraud on the FDA claim (Doc. No. 34).

n1 Because the response contained confidential material, it was submitted under seal pursuant to Judge Bechtel's Pretrial Order Number 7 in MDL 1014.

I. BACKGROUND

This is one of approximately 2300 products liability cases arising out of the surgical use of certain orthopedic hardware, or "bone screws." The hardware in question in this case was originally designed at Texas Scottish Rite Hospital ("TSRH") and is manufactured by Danek Medical, Inc. ("Danek"). The TSRH hardware is regulated by the [*3] FDA pursuant to the Medical Device Amendments ("MDA") to the Federal Food, Drug and Cosmetic Act ("FDCA"). See 21 U.S.C. § 360c; *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 476, 135 L. Ed. 2d 700, 116 S. Ct. 2240 (1996). In 1992, the TSRH hardware was not approved by the FDA for implantation in the spine's pedicles, which are the rearward-facing arches on either side of the vertebral body supporting the lamina. Instead, the FDA had only approved the hardware for

application in the sacrum, or front, of the spine. Despite the fact that the TSRH hardware was not approved by the FDA for use in the pedicles, surgeons had widely adopted it for that purpose. In particular, surgeons would implant TSRH screws into the pedicles in order to align and immobilize the spine after a lumbar fusion operation so as to allow the bone graft to take. Such "off-label" use is not in and of itself illegal. It is Plaintiffs' contention, however, that Danek encouraged the surgeons in this practice, sponsoring seminars on pedicle implantation and generously compensating surgeons who acted as teachers and exponents.

In September of 1992, in hopes of alleviating his chronic back pain, Plaintiff Dean Edgar [*4] underwent surgery to fuse the L-2 and S-1 vertebrae of his spine. The surgery was performed by Dr. Richard Fessler. In order to immobilize Edgar's spine after the operation, Dr. Fessler implanted the TSRH hardware, fixing bone screws in the pedicles at L2 and L4 and in the sacrum at S1. Dr. Fessler later repositioned the sacral screws. In February of 1996, Edgar had the TSRH hardware removed by Dr. David Cahill. Dr. Cahill found that Edgar's spine had successfully fused, and although several pedicle screws had loosened, this was to be expected.

Nonetheless, Edgar's back pain persisted. Prompted by an episode of "20/20" investigating the use of pedicle screws, Edgar and his wife brought this action against Danek, invoking this Court's diversity jurisdiction over their five state law claims. See 28 U.S.C. § 1332. Plaintiffs' complaint contains claims for: negligence (Count I); strict liability (Count II); breach of implied warranty (Count III); fraud (Count IV); and, on the part of Nancy Edgar, breach of consortium (Count V). Pursuant to 18 U.S.C. § 1407, the case was transferred by the Multidistrict Litigation Panel, along with the 2300 other orthopedic bone screw actions, to [*5] the Eastern District of Pennsylvania to be overseen, prior to trial, by Judge Bechtle. In March of 1995, in his Pretrial Order No. 12, Judge Bechtle dismissed the plaintiffs' fraud on the FDA claims, concluding that they were either preempted by the MDA, or, that they represented impermissible implied rights of action under the FDCA. In June of 1996, in *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 476, 135 L. Ed. 2d 700, 116 S. Ct. 2240 (1996), the Supreme Court concluded that the MDA did not enjoy preemptive effect. Nonetheless, Judge Bechtle concluded that his Pretrial Order No. 12 remained intact insofar as Lohr "did not address claims of fraud on the FDA with respect to the absence of a private right of action for violations of the FDCA." Even if such a claim were permissible, Judge Bechtle concluded, it would fail for lack of evidence of proximate causation.

On February 17, 1998, the case was remanded to this Court, and, shortly thereafter, Defendant moved for summary judgment in its favor. On November 19, 1998, the United States Court of Appeals for the Third Circuit ruled that Judge Bechtle had erred in dismissing all the fraud on the FDA claims. See *In re Orthopedic Bone [*6] Screw Prods. Liab. Litig.*, 159 F.3d 817 (3d Cir. 1998). In the wake of the Third Circuit's ruling, the Plaintiffs moved to "reinstate" a fraud on the FDA claim, despite never having pleaded such a claim.

II. DISCUSSION

Presently before the Court, then, are Defendant's motion for summary judgment and Plaintiffs' motion to "reinstate" a fraud on the FDA claim, which the Court will treat as an opposed motion for leave to amend pursuant to Rule 15(a) of the Federal Rules of Civil Procedure.

A. Defendant's Motion for Summary Judgment

Summary Judgment is proper "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to summary judgment as a matter of law." Fed. R. Civ. P. 56(c). Defendant contends that none of Plaintiffs' claims pose a genuine issue of material fact, and thus, it is entitled to complete summary judgment.

1. Negligence

Plaintiffs contend that "Defendant negligently designed, manufactured, assembled and distributed [the TSRH hardware]..." (Compl. P 23.) The elements of a negligence claim are: (1) [*7] the existence of a duty toward the plaintiff; (2) a breach of that duty; and (3) injury to the plaintiff actually and proximately caused by that breach. See *Rupp v. Bryant*, 417 So. 2d 658, 668 n.27 (Fla. 1982). In addition, where the claim for negligence arises in context of product liability, the plaintiff must also show some defect in the product, whether of manufacture or design. See *Barrow v. Bristol-Myers Squibb Co.*, 1998 U.S. Dist. LEXIS 22041, No. 96-689- CIV-ORL-19B, 1998 WL 812318, at *27 (M.D. Fla. Oct. 29, 1998); see also *Bogle v. Sofamor Danek Group, Inc.*, 1999 U.S. Dist. LEXIS 6387, No. 95-8646-CIV-RYSKAMP, slip op. at 7 (S.D. Fla. Mar. 5, 1999).

Defendant points out that Plaintiffs have come forward with no evidence of a defect in either the manufacture or the design of the TSRH hardware. Plaintiffs' evidence on this point is indeed threadbare. Their expert, Dr. Harold Alexander, reports, "It is my belief that there is no sound scientific basis for the utilization of pedicle screw fixation in spinal fusion surgery." (Pls.' Mem. Opp'n Def.'s Mot. Summ. J. Ex. 2 at 10.) Summarizing other

studies, he also notes that "the complication rate of fusion procedures employing screw fixation is significantly higher than the [*8] rate in procedures that do not utilize instrumentation in the fusion procedure as well as procedures that use other, less invasive methods of fixation such as laminar hooks and wires." *Id.* at 11.

Courts presiding over other orthopedic bone screw cases have criticized the generality of these opinions: "The generalities urged against the pedicle screw procedure offered by plaintiff's expert, Dr. Alexander have been rejected time and again by various courts which found him unqualified to offer an opinion or rejected his conclusions, finding that they did not prove a design defect." *McCarthy v. Danek Med., Inc.*, 1999 U.S. Dist. LEXIS 1186, at *8, No. 95-1667, slip op. at 7 (E.D. La. Jan. 5, 1999). Those presiding over cases in which Danek was the Defendant have emphasized that Dr. Alexander never describes just what makes the TSRH hardware defective; indeed, Alexander never addresses the TSRH hardware specifically at all. See *Moeller v. Danek Med., Inc.*, 166 F.3d 1205, slip op. at 5 (3d Cir. 1998) ("Dr. Alexander opines that spine-fixation devices pose risks to their patients, but he does not identify any particular defect in Danek's device."); *Bogle*, slip op. at 10 ("The sum of Dr. Alexander's [*9] testimony fails to identify any particular defect with the product."); *Baker v. Danek Med.*, 35 F. Supp. 2d 875, 1998 WL 968329, at *4 (N.D. Fla. 1998) ("Dr. Alexander's testimony still does not touch upon at all what it is that is defective about the defendants' products, and does not specifically mention the defendants' product in his report.").

This Court, like those courts, concludes that "Dr. Alexander's report adds little evidentiary worth to this case." *Baker*, 1998 WL 968329, at *4. Consequently, this Court follows two recent decisions by the Honorable Richard Lazarra in holding that Plaintiffs have failed to generate a genuine issue of material fact as to the defective manufacture or design of the TSRH hardware. See *Alexander v. Danek*, 37 F. Supp. 2d 1346, 1999 U.S. Dist. LEXIS 4446, 1999 WL 133044, at *4 (M.D. Fla. 1999); *Savage v. Danek Med. Inc.*, 31 F. Supp. 2d 980, 983-84 (M.D. Fla. 1999). Other courts have concluded that summary judgment was proper on the same basis. See *Bogle*, slip op. at 10, 13 (granting summary judgment on negligence and strict liability claims due to absence of evidence of defect in TSRH hardware); *Broderick v. Sofamor Danek [*10] Group, Inc.*, 1999 U.S. Dist. LEXIS 6434, No. 95-8644-CIV-RYSKAMP, slip op. at 10, 15 (S.D. Fla. Apr. 9, 1999) (same); *McDaniel v. Sofamor Danek Group, Inc.*, 1999 U.S. Dist. LEXIS 6435, No. 95-1477-CIV-RYSKAMP, slip op. at 10, 14 (S.D. Fla. Mar. 5, 1999) (same); *Burton v. Danek Med., Inc.*, 1999 U.S. Dist. LEXIS 2619, No. CIV. A. 95-5565, 1999 WL 118020, at

*7 (E.D. Pa. Mar. 1, 1999) (granting summary judgment on strict liability, failure to warn, and breach of implied warranty of merchantability claims due to absence of evidence of defect); *Coleman v. Danek Med., Inc.*, 43 F. Supp. 2d 637, 1999 U.S. Dist. LEXIS 4492, *31, slip op. at 17-22 (S.D. Miss. 1999) (granting summary judgment on strict liability claim due to absence of evidence of defect); *McCarthy*, slip op. at 7 (same); *Love v. Danek Med., Inc.*, 1998 U.S. Dist. LEXIS 19862, No. 3:95-CV-706-S, slip op. at 2-3 (W.D. Ky. Nov. 25, 1998) (same); *Baker*, 1998 WL 968329, at **2-4 (concluding that Dr. Alexander "does not create a triable issue of fact" as to defect); *Talley v. Danek Med., Inc.*, 7 F. Supp. 2d 725, 732 (E.D. Va. 1998) (same); *Theriot v. Danek Med. Inc.*, 1997 U.S. Dist. LEXIS 22879, No. 94-2646, slip op. at 2 (E.D. La. Dec. 5, 1997) (same).

Even if Plaintiffs were able to point to a genuine issue of material fact as to defect, they would still be forced [*11] to come forward with evidence from which a trier of fact could conclude that the defect caused Edgar's subsequent back pain. Dr. Alexander, who is not a medical doctor and whose opinions are not specific to this Plaintiff, can offer no credible testimony as to causation. See *Hill v. Danek Med., Inc.*, 1998 U.S. Dist. LEXIS 21749, *10, No. 4:96-CV-177-H1, slip op. at 7 (E.D.N.C. Sept. 10, 1998) ("This court will not consider Dr. Alexander's report on the critical issue of causation."); *Kirkman v. Sofamor, S.N.C.*, 1998 U.S. Dist. LEXIS 13357, *9, No. 1:98cv100, 1998 WL 666706, at *3 (W.D.N.C. July 21, 1998) ("This Court has previously found that the statements of Dr. Harold Alexander are not admissible as expert medical evidence on causation, as he is not a medical doctor, and his statements are too generalized to have any bearing on this Plaintiff's medical condition.").

Consequently, Plaintiffs must depend on their other expert, Dr. Yarus, in order to create a genuine issue of material fact as to causation. The sum of Dr. Yarus' expert opinion is as follows:

It is my opinion to a reasonable degree of medical certainty that there is an approximate cause of progression of impairment and disability related to the implantation of hardware [*12] utilized in the treatment of Mr. Edgar's low back condition. It is with an equally high degree of medical certainty that medical problems that ensued subsequent to the implementation necessitating removal were directly related to the hardware causing progressive disabling pain and radiating symptomatology.

(Pls.' Mem. Opp'n Def.'s Mot. Summ. J. Ex. 8 at 3.) This analysis consists of nothing more a bare conclusion, which is itself a non sequitur — post hoc ergo propter hoc. The questionable nature of this logic is brought to the fore in the context of expert scientific testimony, where "cau-

sation opinion based solely on a temporal relationship is ... insufficient to satisfy the requirements of Fed. R. Evid. 702." See *Cartwright v. Home Depot U.S.A., Inc.*, 936 F. Supp. 900, 906 (M.D. Fla. 1996). Other courts have dismissed the value of Yarus's opinion on this basis: "[Yarus] simply opines that since plaintiff had pain before surgery and that pain worsened after surgery, the worsened pain must be a result of the instrumentation. The only conclusion to be drawn in this case is that Yarus's testimony was influenced by a litigation-driven financial incentive." *Leigh v. Danek* [*13] *Med., Inc.*, 1998 U.S. Dist. LEXIS 21037, *17, 4:95-CV-797-A, slip op. at 15 (N.D. Tex. Dec. 14, 1998); accord *Baker*, 1998 WL 968329, at *2 ("[Yarus] fail[s] to offer testimony of anything other than a temporal connection between implantation and symptoms suffered by plaintiff.").

The value of Yarus's testimony is diminished further by the fact that Yarus never examined Edgar personally. See *Baker*, 1998 WL 968329, at *3 ("Also, it should be noted that Dr. Yarus did not examine or speak with plaintiff before filing his report."); cf. *Burton*, 1999 WL 118020, at *5 (noting importance of whether expert on causation personally examined plaintiff). Indeed, Yarus could not recall having examined the TSRH hardware itself. (Yarus MDL Dep. at 89.) Yarus's opinion is undermined still further by his failure to conduct a differential diagnosis. Cf. *Burton*, 1999 WL 118020, at *5 (remarking on necessity of differential diagnosis); *Conger v. Danek Med., Inc.*, 1998 U.S. Dist. LEXIS 21038, *16, 4:96cv739A, slip op. at 12-16 (N.D. Tex. Dec. 14, 1998) (same). Finally, it must be noted that Yarus's testimony on the subject of pedicle screws was not an outgrowth of his work or independent research, but stemmed solely from this litigation. Cf. *Burton*, [*14] 1999 WL 118020, at *4 ("One significant consideration is whether the expert is proposing to testify about matters growing naturally and directly out of research conducted independent of the litigation, or whether the expert developed his or her opinions expressly for the purposes of testifying.").

All these factors counsel the Court to accord Yarus's opinion little, if any weight. No reasonable trier of fact could, on the basis of Yarus's bare conclusion, conclude that the screws in the pedicles of Edgar's spine caused his subsequent pain. This Court therefore joins those courts that have concluded that there was insufficient evidence that the TSRH hardware caused plaintiffs' injuries to withstand summary judgment. See *Burton*, 1999 WL 118020, at *5; *Coleman*, slip op. at 17-22; *Peterson v. Danek Med., Inc.*, 1999 U.S. Dist. LEXIS 5289, *3, No. 2:96cv10, slip op. at 5 (W.D.N.C. Feb. 25, 1999); *Hickman v. Sofamor-Danek Group., Inc.*, 1999 U.S. Dist. LEXIS 4384, *19, No. C-95-01095-CW, slip op. at 21 (N.D. Cal. Feb. 17, 1999); *McCarthy*, slip op. at 10; *Conger*, slip op. at 12-

16; *Leigh*, slip op. at 10-14; *Love*, slip op. at 2-3; *Hill*, slip op. at 10. n2

n2 This lack of evidence of causation also is fatal to any claim that Danek's alleged violation of the MDA amendments constituted negligence per se.

[*15]

2. Strict Liability

In *West v. Caterpillar Tractor Co.* the Florida Supreme Court set forth the standard to recover under the theory of strict liability:

In order to hold a manufacturer liable on the theory of strict liability in tort, the user must establish the manufacturer's relationship to the product in question, the defect and unreasonably dangerous condition of the product, and the existence of the proximate causal connection between such condition and the user's injuries or damages.

336 So. 2d 80, 86-87 (Fla. 1976), cited in *Baker*, 1998 WL 968329, at *2. Like Plaintiffs' negligence claim, then, Plaintiffs' strict liability claim depends on sufficient evidence of causation and defect. For the reasons stated supra part II.A.I, therefore, summary judgment is appropriate.

3. Breach of Implied Warranty

There can be no claim for breach of implied warranty in the absence of privity. See *Kramer v. Piper Aircraft Corp.*, 520 So. 2d 37, 39 (Fla. 1988). "A plaintiff who purchases a product, but does not buy it directly from the defendant, is not in privity with that defendant." *T.W.M. v. American Med. Sys., Inc.*, 886 F. Supp. 842, 844 (N.D. Fla. 1995). [*16] Thus, in *Baker v. Danek Medical*, the United States District Court for the Northern District of Florida granted summary judgment for Danek on the plaintiff's breach of implied warranty of merchantability claim, finding no privity between the two. 35 F. Supp. 2d 875, 1998 WL 968329, at *2. This Court concludes that summary judgment is appropriate with regards to the breach of implied warranty claim as well.

4. Fraud / Failure to Warn

According to Plaintiffs' complaint

Defendant, intentionally and unlawfully represented to the Plaintiff that the 'device' was safe and acceptable for use in spinal stabilization surgery by preparing, distributing and publishing videotapes, manuals, patient brochures, and physician manuals all in an effort to market or promote pedicle screw spine fixation systems in violation of FDA regulations which they knew or should have known contained false and fraudulent claims of benefit and risk associated with implantation.

(Compl. P 49.) The dilemma for Plaintiffs is that any misrepresentations on the part of Defendant were not communicated directly to Edgar; instead, Edgar dealt with Dr. Fessler, who was "act[ing] as a learned intermediary between the manufacturer [*17] and the consumer, weigh[ing] the potential benefits against the dangers in deciding whether to recommend the drug to meet the patient's needs." *Christopher v. Cutter Labs*, 53 F.3d 1184, 1192 (11th Cir. 1995); accord *Felix v. Hoffmann-LaRoche, Inc.*, 540 So. 2d 102, 104 (Fla. 1989). In such a situation, in order to recover for a manufacturer's failure to warn, a plaintiff must prove that the manufacturer's failure to warn the physician was the proximate cause of the injuries to the plaintiff. In other words, the plaintiff must show that the physician would not have used the device in question if he or she had been warned by the manufacturer of its risks. A physician's independent awareness of those risks thus disrupts probable cause and obviates any liability for a manufacturer's failure to warn.

In this instance, Dr. Fessler has published research on the use of bone screws in the pedicle of the spine. (Fessler Dep. at 16-18.) He has done as many as one thousand spinal surgeries, including approximately two hundred involving pedicle screws. *Id.* at 73. Moreover, Dr. Fessler has testified to his awareness that the TSRH system had not been approved for implantation in the [*18] pedicles of the spine. *Id.* 59-60. In sum, Dr. Fessler was fully aware of the risks and the status of the TSRH hardware and, specifically, implantation of bone screws into the pedicles. He was, in other words, a "learned intermediary" insulating Danek from liability for failure to warn. n3 The Court's conclusion in this regard comports with its own precedent, see *Alexander*, 1999 WL 133044, at *4; *Savage*, 31 F. Supp. 2d at 984-85, as well as precedent from elsewhere. See *Talley*, 7 F. Supp. 2d at 733. It comports, moreover, with those decisions holding that surgeons implanting TSRH hardware in the pedicles of patients' spines did so without relying on any representations on the part of Danek. See *Burton*, 1999 WL 118020, at *6; *Taylor v. Danek Med., Inc.*, 1998 U.S. Dist. LEXIS 20265, No. CIV. A. 95-7232, 1998 WL 962062, at *6 (E.D. Pa. Dec. 29, 1998); *Bruzer v. Danek Med., Inc.*, 1998 U.S. Dist. LEXIS 19834, No. 3-95-971/RHK/JMM, slip op. at 14 (D. Minn. Oct. 1, 1998); *Baker v. Danek Med., Inc.*, 35 F. Supp. 2d 865, 870 (N.D. Fla. 1998); *Cali v. Danek Med., Inc.*, 24 F. Supp. 2d 941, No. 95-C-753, slip op. at 17-18 (W.D. Wis. 1998); *Coleman*, slip op. at 16; *Theriot*, slip op. at 8-9. n4

n3 To the extent that Plaintiffs' negligence and strict liability claims also implicate a failure to warn, they too are defeated by the learned intermediary doctrine.

[*19]

n4 Summary judgment is also appropriate with regards to the fraud claim because Plaintiffs' have failed to come forward with evidence from which a reasonable trier of fact could conclude that Danek's failure to warn was the proximate cause of Edgar's injury. See *supra* part II.A.2.

5. Loss of Consortium

Because Mrs. Edgar's loss of consortium claim is derivative of Dean Edgar's claims, summary judgment in Defendant's favor as to that claim is likewise appropriate. See, e.g., *Habelow v. Travelers Ins. Co.*, 389 So. 2d 218, 220 (Fla. Dist. Ct. App. 1980).

B. Motion to "Reinstate" a Fraud on the FDA Claim

As noted *supra*, this Court will treat Plaintiffs' motion to "reinstate" a "fraud on the FDA" claim as one to amend their complaint to include such a claim. In situations in which a responsive pleading has been served, Rule 15(a) of the Federal Rules of Civil Procedure provides that a party may amend its pleading by written consent of the adverse party or by leave of the Court. Fed. R. Civ. P. 15(a). Nonetheless, it is well settled that "there is no obligation to allow amendment if [*20] to do so would be futile." *Laborers Local 938 Joint Health & Welfare Trust Fund v. B.R. Starnes Co.*, 827 F.2d 1454, 1456 n.1 (11th Cir. 1987) (citing *Foman v. Davis*, 371 U.S. 178, 182, 9 L. Ed. 2d 222, 83 S. Ct. 227 (1962)). An amendment is futile if the cause of action asserted therein could not withstand a motion to dismiss. *Florida Power & Light Co. v. Allis Chalmers Corp.*, 85 F.3d 1514, 1520 (11th Cir. 1996); *Halliburton & Assocs., Inc. v. Henderson, Few & Co.*, 774 F.2d 441, 444 (11th Cir. 1985). That is, a court may deny leave to amend when it appears beyond doubt that the proponent can prove no set of facts to support the proposed amendment. See Fed. R. Civ. P. 12(b)(6); see also *Conley v. Gibson*, 355 U.S. 41, 45-46, 2 L. Ed. 2d 80, 78 S. Ct. 99 (1957).

Judge Bechtel concluded that the bone screw plaintiffs could not state a claim for "fraud on the FDA" in any jurisdiction. In reaffirming this conclusion in the wake of *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 476, 135 L. Ed. 2d 700, 116 S. Ct. 2240 (1996), Judge Bechtel maintained that Lohr "did not address claims of fraud on the FDA with respect to the absence of a private right of action for violations [*21] of the FDCA." Even if such a claim were permissible, Judge Bechtel concluded, it would fail for lack of evidence of proximate causation.

The Third Circuit reversed on both grounds. See *In re Orthopedic Bone Screw Prods. Liab. Litig.*, 159 F.3d 817 (3d Cir. 1998). With regards to the first, the Court

1999 U.S. Dist. LEXIS 6431, *21; CCH Prod. Liab. Rep. P15,668

of Appeals noted that the impermissible implied right of action argument "was necessarily based on the doctrine of preemption," and, thus, invalid in the wake of Lohr. With regards to Judge Bechtel's conclusion that the fraud on the FDA claims also fail for lack of evidence of causation, the Third Circuit concluded that there were some jurisdictions where this was not the case. These are jurisdictions that have adopted section 310 of the Restatement (Second) of Torts, which allows for liability when a speaker makes a misrepresentation to one person that causes harm to another. See *id. at 826-27*. The Third Circuit noted, however, that "[it] [did] not hold that plaintiffs have or have not alleged a legally sufficient causal nexus." *Id. at 827*. "That issue," it correctly discerned, "can be resolved only after the controlling law has been identified in each case." *Id. [*22]*

This prediction that any fraud on the FDA claim would depend on whether any given jurisdiction has adopted section 310 of the Restatement has been borne out in subsequent bone screw cases. Compare *Loewy v. Stuart Drug & Surgical Supply*, 1999 U.S. Dist. LEXIS 1565, No. 91-CIV-7148-LBS, 1999 WL 76939, at **3-4 (S.D.N.Y. Feb. 11, 1999) (holding that plaintiffs failed to state claim for fraud on the FDA because New York has not adopted section 310), with *Taylor*, 1998 WL 962062, at **5-6 (holding that, because Pennsylvania has adopted section 310, plaintiffs' fraud on the FDA claim did not fail for lack of privity). Florida has not adopted section 310. Under Florida law, an actionable fraudulent misrepresentation is: (1) a false statement of fact; (2) known by the defendant to be false at the time that it was made; (3) made for the purpose of inducing the plaintiff to act in reliance thereon; (4) action by the plaintiff in reliance on the correctness of the representation; and (5) resulting damage or injury to the plaintiff. See *Mosley v. American Medical Int'l, Inc.*, 712 So. 2d 1149, 1151 (Fla. Dist. Ct. App. 1998); *Crown Eurocars, Inc. v. Schropp*, 636 So. 2d 30, 35 n.8 (Fla. Dist. Ct. App. [*23] 1993); *S.H. Inv. & Dev. Corp. v. Kincaid*, 495 So. 2d 768, 770 (Fla. 5th Dist. Ct. App. 1986); see

also *Williams Elec. Co., Inc. v. Honeywell, Inc.*, 772 F. Supp. 1225, 1239 (N.D. Fla. 1991) ("[A] plaintiff must have relied on a defendant's misrepresentations and must have been deceived by them in order to maintain a Florida fraud cause of action."). Thus, this Court holds that, in Florida, Plaintiffs cannot state a claim for fraud on a third party such as the FDA. Consequently, any amendment to include such a claim would be futile, and the motion for leave to amend must be denied.

Accordingly, it is ORDERED AND ADJUDGED that:

(1) Plaintiffs' Motion to Extend Time to File Response to Defendant's Motion for Final Summary Judgment (Doc. No. 29, filed February 1, 1999) is GRANTED;

(2) Defendant's Motion to Extend Time to File Reply Memorandum in Further Support of its Motion for Summary Judgment (Doc. No. 36, filed March 17, 1999) is GRANTED;

(3) Defendant's Motion for Summary Judgment (Doc. No. 22, filed August 6, 1998) is GRANTED;

(4) Plaintiffs' Motion to Reinstate Fraud on the FDA claim (Doc. No. 31, filed February 24, 1999) is DENIED; and

(5) the Clerk is directed to [*24] enter judgment in favor of the Defendant and to close this case.

DONE AND ORDERED at Tampa, Florida, this 31ST day of March, 1999.

SUSAN C. BUCKLEW

United States District Judge

JUDGMENT IN A CIVIL CASE

IT IS ORDERED AND ADJUDGED that judgment is entered in favor of the defendant, DANEK MEDICAL INC.

March 31, 1999

TAB 3

3 of 3 DOCUMENTS

CAROL HELLER and THOMAS HELLER, individually and as the parents and natural guardians of EMILY and KATHERINE HELLER, Plaintiffs v. SHAW INDUSTRIES, INC., Defendant

CIVIL ACTION No. 95-7657

UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

1997 U.S. Dist. LEXIS 12399; CCH Prod. Liab. Rep. P15,050

August 15, 1997, Decided

August 18, 1997, Filed, Entered

DISPOSITION:

[*1] Defendant's motion in limine to exclude expert testimony and motion for summary judgment GRANTED, and judgment entered in favor of the defendant and against the plaintiffs.

than acute, exposure. Consequently, the court granted defendant summary judgment on the defective design claim and failure to warn claim. The court then found that 15 U.S.C.S. § 2310(d) did not provide a private right of action for personal injury and held that the other fraud claims had not been proven.

CASE SUMMARY

PROCEDURAL POSTURE: Defendant carpet manufacturer sought summary judgment on the products liability action brought by plaintiffs, homeowners and children. Plaintiffs also brought claims for breach of warranty under the Magnuson-Moss Act, 15 U.S.C.S. § 2310(d); common law fraud; failure to comply with the Pennsylvania Unfair Trade Practices Act, 73 P.S. §§ 201 et seq.; and for medical monitoring as a toxic tort.

OVERVIEW: Plaintiffs moved into a home and replaced existing carpets with defendant's carpets after experiencing respiratory distress, but the symptoms worsened after receiving the new carpets. The home tested positive for 14 volatile organic compounds (VOC's). The carpets were made of polypropylene and nylon with styrene-butadiene rubber (SBR), or latex, backing. Defendant removed the carpets but the symptoms remained and plaintiffs sold the home. The court found that, absent the unreliable and inadmissible testimony of their experts, plaintiffs provided no evidence that their injuries were caused by defendant's carpeting. The court held that the expert testimony used methods that others had not reproduced and relied on studies that did not link SBR-backed carpets to health problems. Further, the court found that the health levels the experts quoted for VOC's related to long-term, rather

OUTCOME: The court granted defendant's motion in limine to exclude plaintiffs' expert testimony and also granted defendant's motion for summary judgment.

CORE CONCEPTS

Civil Procedure : Summary Judgment : Summary Judgment Standard

Summary judgment is appropriate if the admissible evidence presents no genuine issue of material fact and the moving party is entitled to judgment as a matter of law. The moving party need not produce evidence to disprove the opponent's claim but does carry the burden of demonstrating the absence of any genuine issue of material fact. In turn, the non-moving party cannot rely on the allegations contained in the complaint. Instead, the nonmoving party must offer specific facts indicating that a genuine issue for trial exists. If there are no genuine issues as to material facts, the court must determine whether the moving party is entitled to a judgment as a matter of law. Fed. R. Civ. P. 56(c).

Torts : Products Liability : Duty to Warn

Torts : Products Liability : Strict Liability

Under Pennsylvania law, a manufacturer is strictly liable for injuries caused by a product that is unreasonably dangerous to intended users for its intended use. To establish a claim, the plaintiffs must prove that the product was defective and that such defect caused the plaintiffs' injuries.

To establish liability for failure to warn, plaintiffs must prove that the lack of a warning (a) rendered the product unreasonably dangerous, and (b) was the proximate cause of plaintiffs' injuries.

Torts : Products Liability : Strict Liability

Where plaintiffs allege defective design, the court must conduct a risk-utility analysis to determine as a matter of law whether the product at issue is defective. A product design is defective where the product's condition justifies placing the risk of loss on the manufacturer or supplier because the unavoidable dangers posed by the product outweigh its social utility. If the court determines that the product is defective as alleged, then the case is submitted to the jury to determine whether the facts indicate that when the product left the manufacturer's control it lacked any element necessary to make it safe for its intended use or possessed any feature that rendered it unsafe for its intended use.

Torts : Causation : Proximate Cause

Torts : Products Liability : Breach of Warranty

Torts : Products Liability : Strict Liability

For a defective design and/or manufacture claim, the plaintiff bears the burden of demonstrating proof of causation. Similarly, the absence of proof of causation is fatal to a failure to warn claim. Plaintiffs must show that the harmful result would not have occurred but for the defendant's conduct, and that the causal connection between the defendant's conduct and the plaintiffs' injuries is not remote. Although causation is normally an issue of fact for the jury, the question becomes one of law where the relevant facts are not in dispute and the remoteness of the causal connection between the defendant's negligence and plaintiffs' injuries is clearly apparent.

Environmental Law : Litigation & Administrative Proceedings : Toxic Torts

Torts : Causation : Proximate Cause

Torts : Products Liability : Strict Liability

In toxic tort claims, plaintiffs must prove general and specific causation. General causation addresses whether products of the same nature as defendant's product are capable of causing the type of injuries alleged; specific causation addresses whether defendant's product more likely than not caused injuries in the particular case. To prove specific causation, plaintiffs must prove that (1) that the defendant released toxins into the environment, (2) that plaintiffs were exposed to such toxins, (3) that plaintiffs have an injury, (4) and that the toxins released by defendant caused that injury. The exposure element requires plaintiffs to show that they were exposed to levels that exceed the normal background level, while the causation element requires proof that the dosage and duration of plaintiffs' exposure were at levels that are hazardous to

human beings.

Evidence : Witnesses : Expert Testimony

Where essential elements of plaintiffs' case depend on expert testimony, a determination of defendant's summary judgment motion must be preceded by a determination of the relevance and reliability, and hence admissibility, of the proffered expert testimony. Fed. R. Evid. 702 requires the district court to ensure that any and all scientific testimony and evidence is reliable. Pursuant to Fed. R. Evid. 104(a), the court must make a preliminary assessment of the reasoning or methodology underlying the proffered expert scientific testimony. The district court's gatekeeper role entails the preliminary assessment of the qualifications of the expert, and the reliability and fit of the testimony; the court must ascertain whether the expert is qualified to render an opinion on the subject, whether the methodology or reasoning underlying the testimony is scientifically valid, and whether the opinion can be applied to the facts at issue.

Evidence : Witnesses : Expert Testimony

The party proffering expert testimony must show by a preponderance of evidence that the techniques or principles underlying an opinion are sufficiently reliable so that the opinion will aid the jury in reaching an accurate decision. The expert's opinion must be based on scientific knowledge; that is the methods and procedures must be grounded in science, rather than subjective beliefs or unsupported speculation. To qualify as "scientific knowledge," an inference or assertion must be derived by the scientific method. Proposed testimony must be supported by the appropriate validation—i.e., good grounds based on what is known.

Evidence : Witnesses : Expert Testimony

A trial judge should not exclude evidence merely because he or she disagrees with the expert's conclusions or finds that the expert's techniques have flaws sufficient to render the expert's conclusion inaccurate. The focus must be solely on principles and methodology, not on the conclusions that they generate. Indeed, the fact finder may be assisted in reaching an accurate result by a consideration of the expert's testimony together with an assessment of its flaws. However, where the flaws are large enough that the expert lacks "good grounds" for his or her conclusion, the court should exercise its gatekeeper role and exclude the evidence.

Evidence : Witnesses : Expert Testimony

In determining the validity of the methodology and principles underlying an expert's opinion, the district court should take into consideration the following factors: (1) the existence and maintenance of standards controlling the technique's operation; (2) whether the methodology has been subject to peer review and publication; (3) what the

known or potential rate of error of that technique may be; (4) whether the methodology has been generally accepted in the scientific community; (5) the degree to which the expert is qualified; (6) the novelty of the technique, that is, its relationship to more established modes of scientific analysis; (7) and the non-judicial use to which the scientific technique is put. After assessing the reliability of the evidence, the court must also weigh the danger that the evidence might confuse or mislead the jury through an unwarranted "aura of reliability."

Evidence : Witnesses : Expert Testimony

Additionally, the court must make an independent evaluation of proffered expert testimony to ascertain whether it conforms to the requirements of Fed. R. Evid. 703, which mandates that the facts and data upon which an expert relies in reaching a conclusion must be of a type reasonably relied upon in the particular field. The proper inquiry is not what the court deems reliable but what experts in the relevant discipline deem it to be. However, as it is the judge who makes the determination of reasonable reliance, and for the judge to make the factual determination under Fed. R. Evid. 104(a) that an expert is basing his or her opinion on a type of data reasonably relied upon by experts, the judge must conduct an independent evaluation into reasonableness. The court must ascertain that the expert had good grounds for finding the data reliable and good grounds to rely on this data to draw the conclusion reached by the expert.

Antitrust & Trade Law : Consumer Protection : Magnuson-Moss Warranty Act

A breach of warranty claim under the Magnuson-Moss Act, 15 U.S.C.S. § 2310(d), does not create a private, independent cause of action for personal injury damages arising out of a breach of warranty, absent allegations that defendant violated a specific standard set forth in the act. 15 U.S.C.S. 2311(b)(2). Further, a plaintiff may not maintain a Magnuson-Moss Act claim unless plaintiffs have given defendant an opportunity to cure the alleged breach of warranty. 15 U.S.C.S. § 2310(e).

Torts : Business & Employment Torts : Deceit & Fraud

Under Pennsylvania law, a cause of action for fraud consists of the following elements: (1) a misrepresentation; (2) a fraudulent utterance thereof; (3) an intention by the maker that the recipient will thereby be induced to act; (4) justifiable reliance by the recipient upon the misrepresentation; (5) damage to the recipient as the proximate result. A negligent misrepresentation is a misrepresentation which arises from a want of reasonable care or competence in obtaining or communicating information, as opposed to a fraudulent misrepresentation which involves either a knowing or a reckless communication of a misrepresentation.

Antitrust & Trade Law : Consumer Protection : Deceptive Labeling & Packaging

Torts : Business & Employment Torts : Deceit & Fraud

To maintain a cause of action under the Pennsylvania Unfair Trade Practices Act, 73 P.S. §§ 201 et seq., plaintiffs must show the essential elements of fraud: (1) material misrepresentation of a material fact; (2) scienter; (3) intention by the declarant to induce action; (4) justifiable reliance by the party defrauded by the misrepresentation; and (5) damages to the party defrauded as a proximate result.

Civil Procedure : Dismissal of Actions : Voluntary Dismissal

Voluntary dismissal at the summary judgment stage of the proceedings is a matter for the court's discretion. Fed. R. Civ. P. 41(a)(2). In deciding whether to grant a voluntary dismissal, the court may consider the following factors: (1) the excessive and duplicative expense of a second litigation; (2) the effort and expense incurred by defendant in preparing for trial; (3) the extent to which the current suit has progressed; and (4) plaintiffs' diligence in bringing the motion to dismiss.

Environmental Law : Litigation & Administrative Proceedings : Toxic Torts

Torts : Products Liability : Negligence

To obtain damages for a medical monitoring claim, plaintiffs must establish the following four elements: (1) Plaintiff was significantly exposed to a proven hazardous substance through the negligent action of the defendant. (2) As a proximate result of such exposure, plaintiff suffers a significantly increased risk of contracting a serious latent disease. (3) That increased risk makes periodic examination reasonably necessary. (4) Monitoring and testing procedures exist which make the early detection and treatment of the disease possible and beneficial. Plaintiffs must prove that they were exposed to chemicals beyond what would normally be encountered by a person in everyday life, so that the risk of being injured from the exposure is greater, in some way, than the normal risks all of us encounter in our everyday lives. Additionally, plaintiffs must prove that the increased risks of harm caused by their exposure to toxic substances warrant a change in the medical monitoring that otherwise would be prescribed for them.

COUNSEL:

For CAROL HELLER, THOMAS HELLER, PLAINTIFFS: JOSEPH C. KOHN, KOHN, SAVETT, KLEIN & GRAF, P.C., DAVID G. CONCANNON, KOHN, SWIFT & GRAF, P.C., PHILADELPHIA, PA USA.

For SHAW INDUSTRIES, INC., DEFENDANT:

ANNE M. MANERO, KENT & MCBRIDE, P.C., PHILADELPHIA, PA USA. JOHN F. KENT, LEE ANN JONES, KENT & MC BRIDE, P.C., PHILADELPHIA, PA USA.

For DONALD J. MC CARTY, JR., JOAN S. MC CARTY, MOVANTS: JONATHAN SHUB, ESQ., LEVINE, FISHBEIN, SEDRAN & BERMAN, PHILA, PA USA. HENRY WEBB, GORDON, THOMAS, HONEYWELL, MALANCA, PETERSON AND DAHEIM, TACOMA, WA USA.

For DENNIS ANELLO, JILL ULLIAN, MOVANTS: CHRISTOPHER D. WARREN, DESTEFANO & WARREN, P.C. PHILADELPHIA, PA USA. GLENN D. GOODMAN, LAW OFFICE OF GLENN D. GOODMAN, SPRINGFIELD, MA USA.

For WINSTON INDIVIDUALLY AND ON BEHALF OF HIS DECEASED WIFE AND PLAINTIFF, BETTY BRASWELL, BETTY (DECEASED), MOVANTS: CHARLES J. BRINK, BRINK AND ASSOCIATES, P.C., HOUSTON, TX USA.

JUDGES:

William H. Yohn, Jr., Judge.

OPINIONBY:

William H. Yohn, Jr.

OPINION:

MEMORANDUM

Yohn, J.

August 15, 1997

In September, 1993, plaintiffs Carol and Thomas Heller purchased and moved into a new home with their daughters Katherine and Emily. Sometime after, Carol and Thomas Heller began to experience respiratory problems, including asthma, difficulty breathing, wheezing, coughing, and dizziness. Plaintiffs claim that their illnesses were caused by exposure to a combination of chemicals emitted by newly installed carpets manufactured by defendant Shaw Industries, Inc. Although [*2] defendant subsequently removed the carpets, plaintiffs continued to experience respiratory problems and, as a result, plaintiffs eventually moved out of and sold their home.

Subsequently, plaintiffs filed suit against defendant, alleging claims of breach of warranty, strict liability, negligent and intentional misrepresentation, and violation of Pennsylvania consumer protection laws. Plaintiffs seek to recover for personal injuries, future medical monitoring costs, and punitive damages.

Presently, defendant has moved in limine to exclude the testimony of plaintiffs' expert witnesses. Defendant argues that the opinions of plaintiffs' experts pertaining to causation are not grounded on a scientific methodology and are not reliable. Additionally, defendant has moved for summary judgment on all claims. Defendant contends that plaintiffs have failed to proffer any evidence to establish that defendant's carpets were defective, that the family members' symptoms were caused by defendant's carpets, that plaintiffs suffer a significant increased risk of contacting a serious latent disease, or that medical monitoring and testing procedures exist which make the early detection and treatment [*3] of future disease possible and beneficial.

For the reasons that follow, defendant's motions will be granted.

I. BACKGROUND

On September 30, 1993, plaintiffs purchased and moved into a nine year old house and property located at 1205 Fox Glove Lane, West Chester, Pennsylvania (the "Fox Glove residence"). Shortly after, Thomas Heller began to experience allergy symptoms such as nasal congestion, a sore throat, and a thick nasal discharge.

On November 15, 1993, Thomas Heller sought treatment from Dr. Bennett of Bennett, Mark & Schuster for his symptoms and on December 9, 1993, Thomas consulted Dr. Joseph E. Pappano, an allergist. (Defend. Exhib. F.) Heller informed Pappano that he previously had experienced allergic reactions to cats, and that the prior owner of the Fox Glove residence had owned cats. Pappano concluded that Thomas' symptoms were likely caused by an allergic reaction to residual cat hair and, in the way of remedy, Pappano advised Thomas to remove the old carpets from the house.

On December 13-14, 1993, plaintiffs replaced the existing carpet and carpet pad in the second floor hall, loft, guest room, stairs and first floor master bedroom suit with new carpet [*4] pad and V&K Interiors Sutton Newance carpet (Newance carpet)—an off-white, berber type, synthetic carpet manufactured by defendant. (Plain. Exhib. 1 at 98.) The Newance carpet installed in the Heller home was made from polypropylene and nylon fiber woven to a polypropylene primary and secondary backing, which was then bonded with a two layer styrene-butadiene rubber (SBR), or latex, backing. (Plain. Exhib. S-1 at 38.)

Plaintiffs also replaced the old carpet and pad in the two upstairs bedrooms (Katherine and Emily's rooms) with carpet remnants. Those remnants were not the same brand and color as the Newance carpet. (Plain. Exhib. 2 at 92-93.) Because there was not enough of Emily's style carpet to cover all her closet, plaintiffs used some of the

Newance style carpet in Emily's closet. (Plain. Exhib. 2 at 135.) Later, in March, 1994, plaintiffs replaced the carpet and pad in the family room with hardwood floor. (Plain. Exhib. 1 at 184-85.) In the living room and dining room, plaintiffs kept the existing carpeting. (Plain. Exhib. 1 at 97.)

In the last week of December, 1993, Carol Heller began to experience severe respiratory illness, which became progressively worse throughout the [*5] Winter and Spring of 1994. Carol and Thomas Heller's symptoms included asthma, difficulty breathing, wheezing, coughing and dizziness; Katherine Heller complained of shortness of breath, and appeared off-color. (Plain. Exhib. 1 at 111-125; Exhib. 2 at 100-103; Exhib. 1 at 102-111.)

Thomas and Carol Heller initially sought treatment from Dr. Julio Amadio, who is Carol's father. Amadio referred them to Dr. Pappano and Dr. Edward A. Theurkauf, a pulmonologist. (Plain. Exhib. 6 at 6-9.) On February 15, 1994, Carol Heller visited Pappano, and informed him that she began experiencing mild wheezing during the night starting in early January when she moved her sleeping quarters from the upstairs guest bedroom to the master bedroom on the first floor. Carol further reported that three days previously, she had experienced nausea, vomiting, and a viral type infection, followed by bouts of wheezing and shortness of breath, and that her symptoms improved significantly when she went out of doors. Pappano conducted allergy skin tests on Carol and found that she tested positive to house dust, house dust mites, feathers and dogs, but not to cats, grass or ragweed. Pappano noted that there was no family [*6] history of allergic respiratory disease, with the exception of some mild symptoms that Carol had once experienced when visiting a seashore house in ocean City, New Jersey. Carol also informed Pappano that her home contained newly installed synthetic rugs, and Carol produced a carpet sample for Pappano to examine. Pappano noted that the carpet definitely had a strong chemical odor, and recommended that Heller employ Todd Environmental Consultants (Todd Environmental) to analyze the rug samples and air quality in her home. (Defend. Exhib. H.)

Following Carol's consultation with Pappano, the Heller family took the following measures to isolate the cause of their reaction: (1) encapsulated all their bedding in plastic; (2) hired a house cleaner; (3) removed the family dog from the home; (4) replaced an electronic air-cleaner; (5) replaced all drapes; (6) changed dry cleaners; and (7) purchased a new vacuum cleaner. However, these measures had no effect on their symptoms. (Plain. Exhib. 1 at 180-182; Exhib. 5 at 34-35.)

On February 23, 1994, the Heller family hired Todd Environmental to perform a surface dust analysis and eval-

uation to determine whether dust in the house contained allergens. [*7] The results of these tests, however, proved unremarkable. (Plain. Exhib. 9.)

Carol Heller returned to Dr. Pappano on March 19, 1994. Carol told Pappano that she was continuing to experience wheezing, especially in the mornings.

On March 21, 1994, Carol Heller called defendant to inquire about the carpeting. Her call was referred to Todd Bethel, a chemist then employed by defendant. Carol described to Bethel her family's symptoms and inquired whether he had heard of other customers having severe respiratory problems. Bethel told Carol that he had never heard of anything like that happening, and explained that defendant's carpets carry a "green tag," which indicates that the rugs are safe. (Plain. Exhib. 1 at 168-74.) The next day, Bethel forwarded to Heller a copy of a list of ingredients in plaintiffs' carpeting, and a brochure from the Carpet and Rug Institute (CRI) entitled "Carpet and Indoor Environment." (Plain. Exhib. 1 at 168-201; Exhib. 10 at 3.)

Because of their continuing illnesses, on April 7, 1994, the Heller family moved out of their home.

The next day, Carol Heller visited Dr. Edward A. Theurkauf, a pulmonologist, for treatment of her respiratory illness. Theurkauf [*8] conducted pulmonary function tests on Carol—the results of which were normal—and diagnosed her as suffering from bronchospasms precipitated by environmental factors. (Defend. Exhib. K.) Two weeks later, Carol informed Theurkauf that her symptoms had improved since she had been away from the Fox Glove residence.

On April 14, 1994, Todd Environmental conducted an air monitoring test at the Hellers' home. Todd collected a sample of air over an eight hour period in the walk-in closet of the upstairs bedrooms—Emily's room—and the sample was sent to MDS Laboratories (MDS) for analysis. MDS analyzed the sample with a standard gas chromatography/mass spectroscopy (GCMS) procedure that is capable of detecting and quantifying volatile organic compounds (VOCs) down to less than one part per billion (ppb). The GCMS procedure detected the following levels of VOCs: total VOCs 20.48 ppb; benzene 2.2 ppb; ethyl benzene 0.69 ppb; cumene 0.11 ppb; 1,1,1-Trichloroethane 0.09 ppb; toluene 2.41 ppb; xylene 2.57 ppb; carbon tetrachloride 0.13 ppb; tetrachloroethylene 0.24 ppb; 2 butoxy ethanol 5.6 ppb; propyl benzene 1.62 ppb; 1 ethyl 3 methyl benzene 1.06 ppb; 1 methyl 3 propyl benzene 1.37 ppb; 1 [*9] methyl ethyl benzene 1.25 ppb; and 1 ethyl 4 methyl benzene 1.12 ppb. (Plain. Exhib. 12.) In total, MDS detected 14 different VOCs.

On May 5, 1994, at plaintiffs' request, defendant re-

moved the Newance carpeting from the Fox Glove residence and refunded plaintiffs the amount they had paid for the carpets. (Plain. Exhib. 1 at 174.) After the carpet was removed, the windows were opened and the house was aired. Six days later, Todd Environmental repeated the previously performed air sample test. The results of the second test revealed the following levels of VOCs: benzene 0.55 ppb; toluene 2.62 ppb; ethyl benzene 0.54 ppb; xylene 2.9 ppb; and tetrachloroethylene 0.24 ppb. The test revealed a decrease in the presence of benzene, 2 butoxy ethanol, and various compounds that contain a benzene ring, termed benzene homologues. Further, the total number of types of VOCs decreased from 14 to 5 and the concentration of total VOCs dropped to one third the previous level. (Plain. Exhib. 13.)

Subsequently, plaintiffs replaced their carpeting with superhypoallergenic rugs (which cost more than the Newance carpeting) and on May 11, 1994, plaintiffs visited their home. (Plain. Exhib. at 174.) However, [*10] although they were in the home for only about one hour, Thomas and Carol Heller's symptoms reappeared.

On May 14, 1994, Carol Heller again visited Dr. Pappano. Carol informed Pappano that her symptoms had improved after moving out of the Fox Glove residence, but that her condition deteriorated when she went back to the Fox Glove home.

After having moved out of the home on April 7, 1994, plaintiffs never returned to the house other than to remove their personal belongings because, according to plaintiffs, their symptoms would reappear whenever they visited the residence. In November, 1994, plaintiffs sold their home for less than they paid for the property in September, 1993. Carol Heller claims that although she currently is not receiving any treatment for asthma, she continues to experience some, albeit subdued, symptoms. (Plain. Exhib. 1 at 178-79, 191-96, 209.)

On December 8, 1995, plaintiffs filed suit against defendant, alleging the following counts: (1) breach of warranty in violation of the Magnuson-Moss Act, 15 U.S.C. § 2310(d); (2) failure to warn; (3) negligent and intentional misrepresentation; (4) defective design and/or manufacture; (5) violation of Pennsylvania consumer [*11] protection laws; and (6) medical monitoring. The complaint alleges that the Newance carpets manufactured by defendant emitted toxic substances, such as benzene, toluene, xylene and vinyl chloride, and that such substances caused plaintiffs' present symptoms and significantly enhanced their risk of contracting future illnesses. Plaintiffs aver that since 1980, defendant has known that carpeting can off-gas toxic substances, that consumers exposed to such substances have suffered adverse health effects, and that defendant concealed its knowledge and failed to warn con-

sumers of the health risks posed by its product. Plaintiffs seek damages for losses incurred in having to sell their Fox Glove home, expenses incurred in attempting to ascertain and eliminate the cause of their suffering, pain and suffering, future medical monitoring costs, and punitive damages.

On March 20, 1997, defendant moved for summary judgment and on June 24, 1997, defendant moved in limine to exclude the testimony of Alan Todd and Doctors Amadio, Pappano and Theurkauf with respect to their opinions regarding causation.

From July 21 to 29, 1997, the court conducted an evidentiary hearing on the admissibility [*12] of the testimony of plaintiffs' expert witnesses. At the end of the hearing, plaintiffs withdrew their claims with respect to alleged physical injuries sustained by Thomas, Katherine, and Emily Heller, but continue to pursue their claim with respect to Carol's alleged physical injuries.

II. DISCUSSION

Defendant argues that it is entitled to summary judgment because plaintiffs' expert opinion evidence regarding causation is inadmissible and, therefore, there is insufficient evidence to sustain a jury finding that the Newance carpets were defective and caused plaintiffs' alleged injuries. Defendant contends that the methodologies applied by plaintiffs' experts are not scientific and that the expert's opinions are hence unreliable.

Plaintiffs proffer proof of causation in the form of expert opinion testimony by Alan Todd, an industrial hygienist, and Doctors Julio Amadio, Joseph Pappano and Edward Theurkauf. Plaintiffs contend that Carol Heller suffered environmentally induced asthma caused by a cocktail of seven VOCs emitted by Newance carpet manufactured by defendant. Plaintiffs claim that the particular batch of carpet installed in the Fox Glove residence was defective [*13] in that it emitted dangerously high levels of benzene, 2 butyl ethanol, and five homologues of Benzene (propyl benzene, 1 ethyl 4 methyl benzene, 1 methyl ethyl benzene, 1 ethyl 3 methyl benzene, and 1 methyl 3 propyl benzene), all of which can cause respiratory irritation.

A. Legal Standard

Summary judgment is appropriate if the admissible evidence presents no genuine issue of material fact and the moving party is entitled to judgment as a matter of law. *Sempier v. Johnson & Higgins*, 45 F.3d 724, 727 (3d Cir. 1995) (citing *Chipollini v. Spencer Gifts, Inc.*, 814 F.2d 893, 896 (3d Cir. 1987) (en banc)). The moving party need not produce evidence to disprove the opponent's claim but does carry the burden of demonstrating

the absence of any genuine issue of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323, 91 L. Ed. 2d 265, 106 S. Ct. 2548 (1986). In turn, the non-moving party cannot rely on the allegations contained in the complaint. Instead, the nonmoving party must offer specific facts indicating that a genuine issue for trial exists. *Id.* at 324. If there are no genuine issues as to material facts, the court must determine whether the moving party [*14] is entitled to a judgment as a matter of law. Fed. R. Civ. P. 56(c).

Plaintiffs' have asserted claims of failure to warn and defective design and/or manufacture claims. Under section 402A of the Restatements (Second) of Torts, which was adopted by the Pennsylvania Supreme Court in *Webb v. Zern*, 422 Pa. 424, 220 A.2d 853, 854 (Pa. 1966), a manufacturer is strictly liable for injuries caused by a product that is "unreasonably dangerous to intended users for its intended use." *Parks v. AlliedSignal, Inc.*, 113 F.3d 1327, 1330 (3d Cir. 1997) (quotation omitted). To establish a claim under § 402A, the plaintiffs must prove that the product was defective and that such defect caused the plaintiffs' injuries. See *Berkebile v. Brantly Helicopter Corp.*, 462 Pa. 83, 337 A.2d 893, 898 (Pa. 1975).ⁿ¹ To establish liability for failure to warn, plaintiffs must prove that the lack of a warning (a) rendered the product "unreasonably dangerous," and (b) was the proximate cause of plaintiffs' injuries. *Staymates v. ITT Holub Industries*, 364 Pa. Super. 37, 527 A.2d 140, 147 (Pa. Super. Ct. 1987).

ⁿ¹ As a threshold matter, where plaintiffs allege defective design, the court must conduct a risk-utility analysis to determine as a matter of law whether the product at issue is defective. *Surace v. Caterpillar, Inc.*, 111 F.3d 1039, 1046 (3d Cir. 1997). A product design is defective where the product's condition justifies placing the risk of loss on the manufacturer or supplier because the unavoidable dangers posed by the product outweigh its social utility. *Id.* "If the court determines that the product is defective as alleged, then the case is submitted to the jury to determine whether the facts indicate that when the product left the manufacturer's control it 'lacked any element necessary to make it safe for its intended use or possessed any feature that rendered it unsafe for its intended use.'" *Id.* at 1044 (quoting *Azzarello v. Black Bros. Co.*, 480 Pa. 547, 391 A.2d 1020, 1027 (Pa. 1978)). The court has not conducted a risk-utility analysis to determine whether synthetic carpets made by defendant are defectively designed because that issue was not fully briefed by the parties, and because the court will dispose of the case on causation grounds.

For a defective design and/or manufacture claim, the plaintiff bears the burden of demonstrating proof of causation. See *City of Philadelphia v. Lead Industries Ass'n*, 994 F.2d 112, 123 (3d Cir. 1993); *Robertson v. Allied Signal, Inc.*, 914 F.2d 360, 366 (3d Cir. 1990). Similarly, the absence of proof of causation is fatal to a failure to warn claim. *Staymates*, 527 A.2d at 147. Plaintiffs must show that the harmful result would not have occurred but for the defendant's conduct, and that the causal connection between the defendant's conduct and the plaintiffs' injuries is not remote. See *Robertson*, 914 F.2d at 367. Although causation is normally an issue of fact for the jury, the question becomes one of law where the relevant facts are not in dispute and the remoteness of the causal connection between the defendant's negligence and plaintiffs' injuries is clearly apparent. See *Conti v. Ford Motor Co.*, 743 F.2d 195, 197-98 (3d Cir. 1984).

In toxic tort claims, plaintiffs must prove general and specific causation. See *DeLuca v. Merrell Dow Pharmaceuticals*, 911 F.2d 941, 958 (3d Cir. 1990). General causation addresses whether products of the same nature as defendant's [*16] product are capable of causing the type of injuries alleged here; specific causation addresses whether defendant's product more likely than not caused injuries in this particular case. *Rutigliano v. Valley Business Forms*, 929 F. Supp. 779, 783 (D.N.J. 1996), *aff'd sub nom. Valley Business Forms v. Graphic Fine Colors, Inc.*, , F.3d (3d Cir. June 27, 1997). To prove specific causation, plaintiffs must prove that (1) that the defendant released toxins into the environment, (2) that plaintiffs were exposed to such toxins, (3) that plaintiffs have an injury, (4) and that the toxins released by defendant caused that injury. See *In re TMI*, 67 F.3d 1103, 1118-19 (3d Cir. 1995), *cert. denied*, 116 S. Ct. 1034 (1996); *In re Paoli R.R. Yard PCB Litigation*, 916 F.2d 829, 860 (3d Cir. 1990). The first element represents a combination of the traditional tort elements of duty and breach, while the remaining elements add an exposure prong to the causation and injury requirement. *In re TMI*, 67 F.3d at 1119. The exposure element requires plaintiffs to show that they were exposed to levels that exceed the normal background level, *Id.*, while the causation element [*17] requires proof that the dosage and duration of plaintiffs' exposure were at levels that are hazardous to human beings. See *Mateer v. U.S. Aluminum*, 1989 WL 60442, at *6 (E.D. Pa. June 6, 1989) (holding that plaintiffs "must at a minimum show that their level of exposure created a significant potential health risk."). *Id.*

Where essential elements of plaintiffs' case depend on expert testimony, a determination of defendant's summary judgment motion must be preceded by a determination of the relevance and reliability, and hence admissibility, of the proffered expert testimony. See *Rutigliano*, 929 F.

*Supp. at 783. In Daubert v. Merrell Dow Pharmaceuticals, 509 U.S. 579, 113 S. Ct. 2786, 2795, 125 L. Ed. 2d 469 (1993), the Supreme Court held that Federal Rule of Evidence 702 n2 requires the district court to ensure that any and all scientific testimony and evidence is reliable. Pursuant to Fed. R. Evid. 104(a), n3 the court must make a preliminary assessment of the reasoning or methodology underlying the proffered expert scientific testimony. See Id. at 2796. The district court's gatekeeper role entails the preliminary assessment of the qualifications of the expert, [*18] and the reliability and fit of the testimony; the court must ascertain whether the expert is qualified to render an opinion on the subject, whether the methodology or reasoning underlying the testimony is scientifically valid, and whether the opinion can be applied to the facts at issue. Daubert, 113 S. Ct. at 2796. n4*

n2 Rule 702 provides that:

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

Fed. R. Evid. 702.

n3 Rule 104(a) provides:

Preliminary questions concerning the qualification of a person to be a witness, the existence of privilege, or the admissibility of evidence shall be determined by the court, subject to the provisions of subdivision (b) [pertaining to conditional admissions]. In making its determination it is not bound by the rules of evidence except those with respect to privileges.

Fed. R. Evid. 104(a).

[*19]

n4 Defendant does not challenge the qualifications of plaintiffs' experts or whether their testimony fits the particular disputed factual issues in the case.

The party proffering the testimony must show by a preponderance of evidence that the techniques or principles underlying an opinion are sufficiently reliable so that the opinion will aid the jury in reaching an accurate decision. *DeLuca, 911 F.2d 941 at 956; United States v. Downing, 753 F.2d 1224, 1240 n.21 (3d Cir. 1985)* ("When there is a serious question of reliability of evidence, it is appropriate for the court to exercise some degree of evidentiary screening function."). The expert's opinion must be based on scientific knowledge; that is

the methods and procedures must be grounded in science, rather than "subjective beliefs or unsupported speculation." *Daubert, 113 S. Ct. at 2795.* To qualify as "scientific knowledge," "an inference or assertion must be derived by the scientific method. Proposed testimony must be supported by the appropriate validation—i.e., 'good grounds' based on what is known." *Id.*

The trial judge should [*20] not exclude evidence merely because he or she disagrees with the expert's conclusions or finds that the expert's techniques have flaws sufficient to render the expert's conclusion inaccurate. *In re Paoli R.R. Yard PCB Litigation, 35 F.3d 717, 745 (3d Cir. 1994).* "The focus ... must be solely on principles and methodology, not on the conclusions that they generate." *Daubert, 113 S. Ct. at 2797.* Indeed, the fact finder may be assisted in reaching an accurate result by a consideration of the expert's testimony together with an assessment of its flaws. *In re Paoli 35 F.3d at 745.* However, where the flaws are large enough that the expert lacks "good grounds" for his or her conclusion, the court should exercise its gatekeeper role and exclude the evidence. *Id. at 746.*

In determining the validity of the methodology and principles underlying an expert's opinion, the district court should take into consideration the following factors: (1) the existence and maintenance of standards controlling the technique's operation; (2) whether the methodology has been subject to peer review and publication; (3) what the known or potential rate of error of that technique may be; (4) whether [*21] the methodology has been generally accepted in the scientific community; (5) the degree to which the expert is qualified; (6) the novelty of the technique, that is, its relationship to more established modes of scientific analysis; (7) and the non-judicial use to which the scientific technique is put. *Id. n5*

n5 After assessing the reliability of the evidence, the court must also weigh the danger that the evidence might confuse or mislead the jury through an unwarranted "aura of reliability." *Downing, 753 F.2d at 1239.* This analysis is performed under the rubric of the probative against prejudice balancing test of Fed. R. Evid. 403. In order to exclude evidence under Rule 403, "there must be something particularly confusing about the scientific evidence at issue—something other than general complexity of scientific evidence." *Paoli, 35 F.3d at 747* (emphasis in original). However, Rule 403 is rarely appropriate as a basis for pre-trial exclusion, unless the in limine hearing creates the "virtual surrogate for a trial record." *Id.*

[*22]

Additionally, the court must make an independent evaluation of proffered expert testimony to ascertain whether it conforms to the requirements of Federal Rule of Evidence 703, which mandates that the facts and data upon which an expert relies in reaching a conclusion must be of a type reasonably relied upon in the particular field. *In re Paoli*, 35 F.3d at 747. n6 "The proper inquiry is not what the court deems reliable but what experts in the relevant discipline deem it to be." *DeLuca*, 911 F.2d at 952 (quotation omitted). However, "it is the judge who makes the determination of reasonable reliance, and [] for the judge to make the factual determination under Rule 104(a) that an expert is basing his or her opinion on a type of data reasonably relied upon by experts, the judge must conduct an independent evaluation into reasonableness." *Id.* at 748 (emphasis in original). The court must ascertain that the expert had good grounds for finding the data reliable and good grounds to rely on this data to draw the conclusion reached by the expert. *Id.* at 749. n7

n6 Fed. R. Evid. 703 provides:

The facts and data in the particular case upon which an expert bases an opinion or inference may be those perceived by or made known to the expert at or before trial. If of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject, the facts or data need not be admissible in evidence.

[*23]

n7 In addition, in cases governed by Pennsylvania law, the court must apply the Pennsylvania rule requiring experts to testify that defendant's actions caused plaintiffs' illness with a reasonable degree of medical certainty. See *Paoli*, 35 F.3d at 750-52. The Pennsylvania requirement of reasonable medical certainty is not merely a rule of admissibility but also constitutes part of the plaintiffs' burden of proof under Pennsylvania law. *Id.*

B. The Testimony of Plaintiffs' Experts

i. Alan Todd

Alan Todd, proffered by plaintiffs as an expert in industrial hygiene and environmental assessment and occupational health and safety, opined in his report and at the in limine hearing that Carol Heller's symptoms were caused by exposure to high concentrations of benzene, 2 butoxy ethanol and benzene homologues emanating from the Newance carpeting.

With respect to general causation, defendant argues that the undisputed scientific evidence shows that carpet emissions do not present a risk to human health. n8

Defendant's expert Ronald E. Gots, M.D., Ph.D., testifies that there have been [*24] five significant risk assessment studies of emissions from carpeting, and that each study found that the levels of VOCs emitted from carpets were well below levels anticipated to produce health effects based on available toxicological data. (Defend. Exhib. J at 22.) n9

n8 The following risk assessment studies conducted tests for emissions from nylon, SBR-backed carpets: (1) in 1990, Terra Inc. conducted emission testing on eight SBR-backed carpets; (2) in 1992, the United States Consumer Products Safety Commission conducted emission tests on four carpet samples, two of which were SBR-backed; (3) in 1992, the Research Triangle Institute performed a risk analysis on emissions from nineteen different carpet samples, all of which were SBR-backed carpets; (4) in 1994, Environ. Corp. conducted a risk analysis of chemicals found to be emitted from new carpets; and (5) in 1994, Alan Hedge, Ph.D. and Rodney Dietert, Ph.D. of Cornell University prepared a review summarizing the current literature concerning chemical emissions from new carpets and their potential for toxicity. All five studies concluded that SBR-backed carpeting poses no significant health threat.

[*25]

n9 Plaintiffs argue that defendant's own internal memoranda reveal that the five emissions studies are not scientifically valid. Plaintiffs note that none of the studies is published, and that the studies surveyed a relatively small number of VOCs emitted from a statistically insignificant number of carpets. Moreover, plaintiffs contend that the studies were developed by defendant and the carpet industry as part of a public relations effort to portray the industry in a favorable light. Plaintiffs quote Carey Mitchell, defendant's expert witness on the subject of carpet emission research, who characterized the research as "political rather than scientific." (Plain. Exhib. 34.)

At the in limine hearing, Todd opined that SBR-backed carpeting can cause the type of symptoms experienced by Carol Heller. To support his opinion, Todd cited the following: research conducted in Scandinavia pertaining to "sick building syndrome" n10; various defendant internal memoranda acknowledging that carpets emit VOCs; and records of numerous consumer inquiries and complaints to defendant, CRI, and the government [*26] concerning carpet odors and related health risks.

n10 See Lars Molhave, Volatile Organic Compounds, Indoor Air Quality and Health, Proceedings of 5th International Conference on Indoor Air Quality and Climate (1990) (Plain. Exhib. 17); Dan Norback and Margareta Torgen, A Longitudinal Study Relating Carpeting With Sick Building Syndrome, 15 *Envtl. Int'l* 129-35 (1989) (Plain. Exhib. 18); B. Seifert, D. Ullrich and R. Nagel, Volatile Organic Compounds from Carpeting, Proceedings of the 8th World Clean Air Congress (1989) (Plain. Exhib. 19); Dawn Tharr, Organic Vapor Emissions from Wall-to-Wall Carpets as a Source of Indoor Air Pollution, 11(5) *Appl. Occup. Env'tl. Hyg.* 436-39 (1996) (Plain. Exhib. 20).

The court finds that the information cited by Todd does not support his conclusion that SBR-backed carpets can cause the types of symptoms experienced by Carol Heller. The publications relied on by Todd do not support his claim that SBR-backed carpeting can cause respiratory illness. The first article, [*27] by Lars Molhave, does not relate to carpeting but solely addresses the health effects of various VOC exposures. (Plain. Exhib. 17.) The second article, by Dan Norback and Margareta Torgen, reports a correlation between wall-to-wall carpeting and the frequency of respiratory symptoms among children in schools in Sweden. The carpets involved, however, had been installed eight to ten years earlier and the authors of the article specifically state that chemical emission from the carpeting was a less probable cause of the children's symptoms. (Plain. Exhib. 18.) The third article, by B. Seifert, D. Ullrich and R. Nagel, reports the results of chamber and field tests for VOC emissions from new carpeting. The authors conclude that although the new carpeting emitted 4 phenylcyclohexane, styrene and 2 ethylhexanol, it was the adhesives used to fix the carpet that emitted general aromatic hydrocarbons at sufficiently levels to explain complaints like those associated with "sick building syndrome." (Plain. Exhib. 19.) Here, there is no dispute that the Newance carpet was not installed with adhesives. The fourth article, by Dawn Tharr, reports the results of ambient air quality tests conducted [*28] in rooms containing newly installed, wall to wall, glued down, SBR-backed carpets. Tharr discovered that the new carpets emitted a complex mixture of refined petroleum solvents, and that the majority of the solvents were released in the first few days after installation. However, Tharr reports that "none of the measured air concentrations approached the reported sensory thresholds." (Plain. Exhib. 20.)

Similarly, the defendant memoranda cited by Todd are not of the type of evidence upon which an expert

would reasonably rely in concluding that carpets can cause asthma. See *Paoli*, 35 *F.3d* at 749. Although Todd has not elaborated on the significance of the defendant memoranda and customer complaints, plaintiffs submitted copies of that information in their summary judgment exhibits and discussed its import in their summary judgment briefs. The submitted evidence consists of memoranda in which existing and former employees of defendant acknowledge that new carpets emit VOCs, specifically toluene, 2 butoxy ethanol, 4 phenylcyclohexane, toluene, benzene, 1,1,1-trichloroethane, methylene chloride, and chloroform. Although the submitted memoranda reveal that defendant was aware that new [*29] carpets emit VOCs, the memoranda do not reveal what level of VOC emissions had been discovered by defendant, or whether the reported emissions were at a levels known to be hazardous to health. n11

n11 Plaintiffs also discuss a 1985 letter from E.C. Roberts, Ph.D., the manager of the Measurements Department of WestPoint Pepperell Research Center, to Carey Mitchell, defendant's Director of Technical Services. Roberts reported a pattern of complaints and reported symptoms associated with new carpet installations, and described air sample tests conducted by an unnamed school, which detected the presence of 58 chemicals emitted by carpet nearly two months after installation.

Again, the large number of complaints cited by plaintiffs regarding new carpet emissions do not establish general causation because plaintiffs offer no evidence to show that such complaints concern incidents substantial similar to the incident here. See *Spino v. John S. Tilley Ladder Co.*, 1997 WL 329133, at *2 (Pa. June 17, 1997)(holding that [*30] evidence concerning other accidents involving the instrumentality that causes the present harm is relevant to prove causation where the other accidents were sufficiently similar to plaintiff's accident); *DiFrischia v. New York Central Railroad Co.*, 307 *F.2d* 473, 476 (3d Cir. 1962). Plaintiffs relate details of two specific instances in which consumers have developed breathing difficulties after having new carpets installed. (Plain. Exhib. S-8, S-9.) However, plaintiffs have not established that those instances involved facts and circumstances sufficiently similar to the facts and circumstance here. Similarly, plaintiffs submit no evidence regarding the nature of the other inquiries and complaints received by defendant, CRI, or the government.

Regarding specific causation, Todd posits that Carol Heller's illness was caused by dangerously high levels of benzene, 2 butoxy ethanol and five benzene homologues emitted by the Newance carpet installed at the Fox Glove

residence. Todd estimates that the total ambient air concentration of the above seven hydrocarbons in the Heller residence after the initial 24 hour period following the installation of the rugs in mid-December, 1993 was [*31] over 52.71552 parts per million (ppm) or 52,715.52 ppb, and that the concentration of benzene alone was 6.84032 ppm or 6,840.32 ppb. Todd believes that such exposure exceeds the Permissible Exposure Limits (PELs) promulgated as workplace standards by the Occupational Safety and Health Administration (OSHA) and the Threshold Limit Values (TLV), which are workplace exposure guidelines derived by the American Conference of Governmental Industrial Hygienists (ACGIH). In addition, Todd cites a Scandinavian study that suggest that exposure to total VOC concentrations of over 7.8 ppm for fifty minutes or more may be expected to cause toxic effects.

In his analysis, Todd applied a two step methodology: the court will refer to the first step as the subtraction method and the second step as the back-extrapolation method. Todd used his subtraction method to calculate what amount of the VOCs detected in the Heller home in April, 1994 can be attributed to the Newance carpets; Todd then applied his back-extrapolation method to the data obtained from the subtraction method to estimate the levels of VOCs emitted by the Newance carpet when it was installed in the home in December, 1993.

The subtraction [*32] method involves the following. On April 14, 1994, Todd Environmental collected an air sample from the closet in Emily's bedroom using an EPA approved collection technique classified as TO1. The TO1 test equipment extracted ambient air from the closet and passed it through a cartridge in which highly volatile VOCs were trapped on a Tenax resin. After eight hours, Todd removed the cartridge from the sampling equipment and forwarded it to MDS, where the Tenax resin sample was analyzed using the GCMS procedure, in which VOCs were purged from the resin sample with an inert gas and placed in a gas chromatography column at low temperature. The column was then heated and the components eluting were identified by mass spectrometry. The results were depicted on a total ion chromatogram, in which the various peaks readings revealed the presence and amounts of various individual VOCs. On May 5, 1994, Todd Environmental repeated the same tests, only this time using collection method TO2, which utilizes a carbon molecular sieve absorbent instead of a Tenax resin, and which utilizes a different purging technique. Subsequently, comparing the results of the April and May tests, Todd noted that the [*33] concentrations in the closet of benzene, 2 Butoxy ethanol and the five benzene homologues had decreased sharply from April to May, 1994. Todd posits that the cause of the decrease in

the concentrations of those compounds was the fact that the Newance carpet had in the meantime been removed from the house. Todd notes that no other changes had occurred to the residence between the two tests, and that the house had been empty of occupants. Thus, Todd opines that the concentration of VOCs that can be attributed to the Newance carpets equals the concentrations detected in the April minus the concentrations detected in May. Based on that formula, Todd declares that in April, 1994, the Newance carpeting was responsible for the following concentrations of VOCs in the Heller home: benzene 1.67 ppb; 2 butoxy ethanol 5.52 ppb; and benzene homologues 5.68 ppb.

For the next part of his analysis, Todd calculated VOC levels emitted by the Newance carpet in December, 1993 by back-extrapolating from the April VOC levels. Todd posits that the VOCs in the headspace over the carpet disperse in a geometric progression, i.e., VOC concentrations decrease by one half at regular intervals or half-lives. Todd's [*34] postulate is derived from the results of various small and large chamber carpet emission tests. In those tests, researchers placed carpet samples in sealed chambers, passed a known volume of clean air through the chamber, recollected the air, and measured it for VOC concentrations. Applying known parameters, the researchers then converted the discovered concentrations into rates of emission in milligrams per meter square of carpet per period of time.

Todd asserts that the carpet study tests reveal that emissions of 4 phenylcyclohexane (4-PCH)—the chemical that produces the characteristic new carpet odor—decrease by 50% every eight days. Based on that observation, Todd contends that ambient air concentrations of 4 PCH also decrease in a geometric progression, and that emissions and concentrations of other VOCs decrease in a similar fashion, albeit with differing half-lives. n12 For the purpose of calculating the previous levels for benzene, 2 butoxy ethanol and the benzene homologues, Todd chooses a ten day half-life because although benzene and the benzene homologues are more volatile than 4 PCH and dissipate quicker, 2 butoxy ethanol has a low vapor pressure and is more soluble [*35] and, thus, off-gasses at a much slower rate than 4 PCH. Consequently, Todd theorizes that the seven VOCs that he attributes to the Newance carpeting have an average half-life of ten days, i.e., the concentrations of those compounds decreases by 50% every ten days.

n12 Todd also testified at the in limine hearing that benzene levels in the blood stream decrease in a geometric progression.

Based on his ten day half life theory, Todd calculates

that the concentrations of the VOCs detected in April, 1994, and attributed by Todd to the Newance carpet were 4096 times higher in December, 1993 because in the 120 day period between December and April, the concentrations of the VOCs went through twelve half-lives, i.e., the concentrations decreased by 50% twelve separate times. Therefore, according to Todd, the levels in December, 1993 were 4096 times higher than in April, 1994; the concentration of benzene in the Heller home was 6,840.32 ppb, the combined concentration of 2 butoxy ethanol and the 5 benzene homologues [*36] was 45,875.2 ppb, and the total concentration of all seven VOCs was 52,715.52 ppb.

Finally, Todd opines that the concentrations of VOCs calculated by using his back extrapolation method are sufficiently high to have caused Carol Heller's alleged symptoms because those levels greatly exceeded OSHA and TLV safety standards as modified for residential settings.

After careful consideration of the principles and theories applied by Todd, the court concludes that Todd's opinion is unreliable because the reasoning and methodology underlying his testimony is not scientifically valid. First, neither Todd nor any other researcher has tested Todd's subtraction and back-extrapolation methodologies to see whether the given results are reproducible. See *Daubert*, 113 S. Ct. at 2796 ("Scientific methodology today is based on generating hypotheses; and testing them to see if they can be falsified"). Similarly, Todd's theories have not been published and subjected to peer review. Although publication is not the sine qua non of admissibility, "submission to the scrutiny of the scientific community is a component of 'good science,' in part because it increases the likelihood that substantive [*37] flaws in methodology will be detected." *Id.* at 2797.

With respect to Todd's subtraction method, Todd did not conduct further tests to ascertain whether changes in the levels of VOCs were attributable to the removal of the carpet or whether the changes were attributable to the natural fluctuation in VOC levels within the home. At the in limine hearing, Todd conceded that the VOC levels detected were close to background rates; Todd testified that the background rate for benzene was 2.0 to 0.5 ppb and, although he has never seen a study of the normal range of benzene, Todd acknowledged that 2.22 ppb was within the normal range for benzene. With respect to 2 butoxy ethanol and the benzene homologues, Todd testified that there is no published study of the background rates, and he has not conducted any tests to determine the background rates of those VOCs. However, in his report, defendant's expert Alfred Hodgson testified that in tests conducted in 12 office buildings in California, the geometric concen-

tration of 2 butoxy ethanol was 1.6 ppb with a geometric standard deviation of plus or minus 3.7 ppb, and the geometric average concentration of benzene was 1 ppb with a standard [*38] deviation of 2.7 ppb. (Defend. in limine Hearing Exhib. 23 at 6.) At the in limine hearing, Hodgson opined that the typical range for benzene found within the home is 1 to 3 ppb, and the typical level range for 2 butoxy ethanol is 0.4 to 27 ppb. Defendant's other expert, Ronald E. Gots, testified at the hearing that the average ambient concentration in the home of benzene ranges from 1.6 to 11 ppb, and of 2 butoxy ethanol ranges from 0.2 to 8 ppb. Those averages are derived from the Environmental Protection Agency (EPA) Total Exposure Assessment Methodology study (Team study), n13 a 1996 benzene exposure study conducted by Lance Wallace, n14 and the EPA's 1988 National Ambient Volatile Organic Data Base. n15 Here, the Heller home had 2.2 ppb of benzene and 5.6 ppb of 2 butoxy ethanol. Consequently, the VOC concentrations detected by Todd Environmental were all within background ranges. n16

n13 The TEAM study conducted air monitoring tests for VOCs in 600,000 homes throughout the United States between 1980 and 1987.

n14 See Lance Wallace, Environmental Exposure to Benzene: An update, 104 Environ. Health Perspectives Supp. 6 at 1129 (1996) (Defend. in limine Hearing Exhib. 11).

[*39]

n15 That study did not research 2 butoxy ethanol levels.

n16 Plaintiffs proffered no evidence with respect to either the background levels or sensory threshold levels for the benzene homologues.

Additionally, Todd did not take any steps to insure that other variables did not effect the air sampling tests. Todd did not measure the air flow or ventilation rates in the closet, no inventory was made of the contents of the closet, and Todd did not personally perform the May, 1994 tests. Further, Todd did not perform any closed chamber tests on a sample of the Newance carpet to verify the source of the VOCs. The American Society for Testing and Materials (ASTM) has validated a procedure for small-scale environmental chamber tests of organic emissions from indoor materials and products, designated as ASTM D 5116-90. n17 (Defend. in limine Hearing Exhib. 1.) The use of that procedure would have enabled Todd to measure the exact level of VOC emissions from the carpet and to verify the accuracy of his subtraction method.

n17 In the 1991 Carpet Policy Dialogue

Compendium report Discussion draft, the Environmental Protection Agency (EPA) adopted ASTM D5116-90 as the appropriate procedure for testing emissions from carpets. (Defend. in limine Hearing Exhib. 2 at 2.1.)

[*40]

Ironically, it is Todd's back extrapolation method that delivers the coup de grace to his subtraction method. Todd posits that the difference in the VOC concentrations in the bedroom closet between April and May, 1994 was caused by the removal of the Newance carpets because everything else in the closet was unchanged. However, according to Todd's back-extrapolation method, in the twenty days between the April and May tests, the amount of VOCs emitted by the carpeting went through two half lives, i.e., the VOC levels were reduced to 25% of previous levels. Thus for benzene, which had a recorded concentration in April of 2.2 ppb., Todd's back-extrapolation method would predict that the recorded concentrations of benzene in May would be 0.55 ppb, even if the carpet was not removed from the home. The exact concentration of benzene detected in May, 1994 was 0.55 ppb. Therefore, Todd cannot claim that the difference in the concentration of benzene between April and May, 1994 is solely attributable to the removal of the Newance carpets when, according to Todd's back-extrapolation theory, the difference is attributable to benzene's ten day half-life decay.

Similarly, Todd performed no [*41] testing of his back-extrapolation methodology to see if his results are reproducible. Todd has not written up his back-extrapolation method and there is therefore no peer review of his method. Further, Todd testified that to his knowledge no one else has ever tried to use the same method, and that there is no peer review for any four to five month back-extrapolation of carpet emissions.

Moreover, the results from small and large chamber carpet emissions tests undermine the postulates upon which Todd's back-extrapolation method is based. At first blush, it is difficult to determine whether the prior studies corroborate Todd's calculations because Todd's measurements involve VOC concentrations in ppm and ppb, while the carpet emission studies reported their findings as emissions in the metric of milligrams of VOC per meter square of carpet. Even where the carpet studies discussed concentrations, the studies employed the metric of micrograms per cubic meter. Further, there is no published information concerning the half-life of benzene.

Nevertheless, the carpet study results reveal that Todd's half-life theory is not grounded in science in that emissions from carpets do not decrease [*42] in a geometric progression over the first four months following

installation; rather, carpet VOC emissions decrease rapidly in the first few days, after which the rate of decrease slows until by the fourteenth day after installation, VOC emissions are at background levels. (Plain. Exhib. 20; Exhib. 36; Exhib. 45.) Professor Alfred T. Hodgson, who has performed closed chamber carpet emission studies at the Indoor Environment Program, Environmental Energy Technology Division, of the Lawrence Berkeley National Laboratories, testified for defendant that although emission rates do decline exponentially if an emitting substance is present and air flow rates are steady, the emitting curve is exponential for a very short time. Hodgson states in his report that "the scientific literature does not support the assumption of an exponential decay for even a period as short as one week." n18 (Defend in limine Hearing Exhib. 23 at 18.) Furthermore, Hodgson testified at the hearing that the same exponential decline phenomena does not apply to VOC concentrations in air. Hodgson explained that emission rates and air concentrations measure different phenomena: emission rates describe the amount of [*43] VOCs released from an emitting substance during a stated period of time; air concentrations measure the total number of molecules or the mass of VOCs in a set amount or volume of air. While emission rates initially may be exponential, the same is not necessarily true for air concentrations within a room because air concentrations are largely affected by ventilation rate. Moreover, no chamber emissions studies have ever detected emissions of benzene, 2 butoxy ethanol or benzene homologues in anywhere close to the levels back-extrapolated by Todd. n19 Consequently, there is no support for Todd's hypotheses that the concentrations of benzene, 2 butoxy ethanol, and the benzene homologues will continue to decrease by 50% every ten days for up to four months after installation. n20

n18 Todd conceded at the in limine hearing that he had never seen a decay curve for benzene or 2 butoxy ethanol.

n19 The 1991 Terra study detected emissions of 2 butoxy ethanol for seven of the eight samples of carpet tested. However, the highest air concentration of 2 butoxy ethanol detected was 4.5 micrograms per cubic meter, or under 1 ppb. (Defend. in limine Hearing Exhib. 14 at A-9.)

[*44]

n20 In their reply memorandum to defendant's motion in limine, plaintiffs submit the affidavit of Kenneth P. Reed, Ph.D, who testified that Todd's calculation of the December, 1993 emission levels is valid and that the methodology employed is generally accepted within the scientific community. Reed explains that he used the same methodology

when testifying in a similar case in Louisiana state court. Further, Reed makes his own calculation of the VOC concentration in December, 1993; Reed concludes that the concentration of VOCs at the time of installation was 50 milligrams per cubic meter (mg/m³). (Plain. Motion In Limine, Exhib. L at P 6.)

However, the court and not Dr. Reed must decide whether Todd's opinion is reliable, and Reed's conclusory statements add little to an analysis of the validity of Todd's methodology. Moreover, Reed's research and opinions were not relied upon by any of plaintiffs' experts, and plaintiffs did not call Reed to testify at the in limine hearing.

A further factor pertinent to reliability is the known or potential rate of error of the method. At the [*45] in limine hearing, Todd testified that his estimate of VOC levels for December, 1993 could be off by as much as 100%. Such a margin of error casts further doubt on the reliability of Todd's VOC projections. n21

n21 Todd has changed his estimate of VOC levels for December, 1993 four times; each time he has greatly increased the size of his estimate. In his initial report, Todd stated that the total concentration of VOCs was 20.48 ppb in mid-April, 1994, and that the concentration of VOCs in December, 1993 would have been two fold and more likely 10 fold higher, i.e. approximately 200 ppb or 0.2 ppm. Based on that estimate, Todd concluded that "off-gassing from the Shaw manufactured carpeting installed in the residence in December 1993 was the likely source of the irritation and related responses." (Defend. Exhib. J at 12.) Second, at his first deposition, Todd testified that the December, 1993 levels were 50 to 100 times higher than the levels detected in April, 1994. Third, in Todd's addendum report, Todd stated that the December levels were 1024 times higher than in April. Finally, at the in limine hearing, Todd testified that the December concentrations were 4096 times higher than the April concentrations.

[*46]

With the exception to Todd's qualifications, the remaining factors for consideration in determining reliability all weigh against admitting Todd's opinion. There is some evidence that Todd's subtraction method is not novel and has non-judicial uses. Todd testified that he has used his subtraction method in EPA air quality compliance test. Similarly, defendant's expert Hodgson, who has previously conducted studies of VOC emissions from car-

pets in a residential test site, employed a similar subtraction method to distinguishing carpet VOC emissions from VOC background levels. In contrast, however, Todd's back extrapolation method is novel, it has not been put to any non-judicial uses, and there is no evidence of record that Todd's theory is generally accepted by the scientific community.

Even if the court were to admit Todd's testimony regarding post-installation emission rates, Todd's opinion must nevertheless be discarded because Todd offered no support for his contention that benzene, 2 butoxy ethanol or benzene homologues can in general, or in the specific concentrations calculated by Todd, cause the type of illness allegedly experienced by Carol Heller. Plaintiffs' expert Ronald [*47] E. Gots, M.D., Ph.D. testifies that benzene does not produce allergies and is not an asthmogenic, except at extremely high levels of hundreds of ppm. (Defend. Exhib. J at 11.) Similarly, plaintiffs offer no proof that 2 butoxy ethanol can cause asthma or allergies.

Todd concedes that the relevant compounds are not allergenic or asthmogenic, but posits that the compounds are irritants when present at sufficiently high levels of exposure. At the in limine hearing, Todd testified that Scandinavian research supports his opinion that the levels of benzene, 2 butoxy ethanol and benzene homologues estimated for December, 1993 are sufficient to have caused Carol's symptoms. In one article, Lars Molhave n22—a professor at the University of Aarhus, Denmark—states that discomfort is expected when total VOC emission levels in a residential setting exceed 3.0 milligrams per cubic meter (mg/m³), n23 and that levels in excess of 8 mg/m³ produce perceived odor and acute irritation. Additionally, Molhave states that exposure to levels of 25 mg/m³ seems to cause weak environmental stress symptoms such as headaches and drowsiness, and associated psychological effects like changed performance, [*48] confusion, and fatigue. (Plain. Exhib. 17 at 10.) However, Molhave cites total VOCs and not the specific VOCs discussed by Todd. Further, Molhave's article discusses VOC concentrations in milligrams per cubic meter, while Todd's report uses the parts per million/billion scale. In their reply memorandum, plaintiffs have converted Molhave's data into parts per million/billion in order to compare Molhave's limits with Todd's estimates. However, the court is unable to verify the accuracy of plaintiffs' data conversion because plaintiffs have not explained what formula was used. n24 Consequently, the threshold limits stated by the Molhave article are not stated in data that have meaning to the issues here.

n22 See Lars Molhave, Volatile Organic Compounds, Indoor Air Quality and Health,

Proceedings of 5th International Conference on Indoor Air Quality and Climate (1990) (Plain. Exhib. 17).

n23 Although Molhave notes that investigations found that complaints seem to be present when VOC concentrations exceed 1.7 mg/m³, in the same paragraph Molhave states that concentrations reported from field investigators were improperly investigated and may be biased. (Plain. Exhib. 17 at 9.)

[*49]

n24 The formula for converting concentrations in parts per million/billion into concentrations in milligrams per cubic meter includes variables for molecular weight, temperature and pressure. Ten parts per million of a hydrocarbon with a low molecular weight weigh less—and therefore measure less in milligrams per cubic meter—than ten parts per million of a hydrocarbon with a higher molecular weight. (See Defend. in limine Hearing Exhib. 23 at 19–20.)

Additionally, Todd asserts that his estimated VOC levels for December, 1993 exceed the OSHA and TLV standards as modified for residential locations. Todd testified at the in limine hearing that the OSHA permissible exposure level for benzene is 10 ppm, the TLV for benzene is 5 ppm, and the TLV for 2 butoxy ethanol is 25 ppm. (Plain. in limine Hearing Exhib. 14, A Safety Assessment of Carpet Emissions by Terra, Inc. at 7). Todd states that these standards were derived for industrial settings, and that to obtain similar standard for residential environments, the PEL and TLV levels must be divided by 100. Todd argues that such an adjustment [*50] is accepted practice because individuals spend more time in the home, and because acceptable levels of exposure are lower where the individuals exposed may be elderly, children or pregnant women. Todd opines that his 100 fold adjustment is conservative in that the 1991 Terra study on carpet emissions applied a 420 safety factor to ensure that individuals who may be more sensitive than the normal factory worker are protected. Consequently, Todd believes that the residential TLV for benzene is 50 ppb, and for 2 butoxy ethanol is 250 ppb.

However, the OSHA and TLV standards cited by Todd relate to long term exposure risks. The modified residential TLVs cited in the Terra study are defined as the maximum "concentration of chemical which under continuous exposure conditions is expected to be devoid of all acute and chronic toxicities." (Plain. in limine Hearing Exhib. 14 at 3.) According to Todd's own back-extrapolation estimate, the levels of benzene and 2 butoxy ethanol

were above the residential TLVs for only 80 days. n25 Moreover, at the in limine hearing, Todd conceded that the OSHA and TLV standards do not relate to asthma or allergy, but to long term health risks for cancer [*51] and leukemia. n26

n25 Further, Todd's causation theory does not explain why Thomas and Carol still continued to experience symptoms after the concentration of VOCs declined following the initial period of time after the carpet was installed. Further, Todd's theory does not explain why persons who visited plaintiffs' home in February and March, 1994 allegedly experienced an allergic reaction. Plaintiffs state that Thomas Heller's sister, Patricia Heller, experienced coughing, difficulty breathing, irritation and "feeling like [she] had sand in her lungs[]" when she spent the weekend with plaintiffs at Easter, 1994. Similarly, plaintiffs claim that Dan Smith, who visited the Heller home in February or March, 1994, experienced a burning sensation in his nose, throat and eyes, difficulty breathing and an ill feeling after his visit.

Alternatively, plaintiffs argue that the latex backing in the carpeting became delaminated, producing off-white sandy particles, and that such particles remained in the home after the carpets were removed, thus precipitating plaintiffs' continued allergic reaction. Plaintiffs, however, have failed to proffer evidence that the delamination process produces chemicals harmful to human health. Plaintiffs contend that, "it is well known that the inhalation of latex particles can cause severe asthmatic attacks, sensory irritation and dermatological irritation." (Plain. Memo. in Opp. to S.J. at 17.) As support for that assertion, plaintiffs cite defendant's expert Dr. S. Michael Phillips, M.D. (Plain. Exhib. 15 at 226–31.) However, Phillips specifically states that the particles produced by carpet delamination cannot cause health problems because the particles produced are too large to be absorbed through inhalation. (Id.)

Recently, plaintiffs suggest that Carol experienced symptoms after the carpet had been removed because of the "sink effect" mentioned by Hodgson, who testified at the hearing that surfaces within a room absorb VOCs and re-emit them at a later time. Plaintiffs opine that re-emitted VOCs caused Carol to feel sick when she returned to the home in May, 1994. However, even if some VOCs originally emitted by the carpets were re-emitted by the room surfaces, the May, 1994 air sample tests reveal that after the carpet was removed, VOC concentrations

in the home were at background levels, and were too low to have caused any physical effect.

[*52]

n26 In addition, plaintiffs have not presented any evidence that the actual levels of VOCs detected in April and May, 1994 exceeded levels harmful to human health.

Consequently, because there are no good scientific grounds to support crucial elements of Todd's opinion, the court will exclude his testimony regarding causation.

ii. Joseph Pappano

Doctor Joseph Pappano opines that VOCs, especially Benzene, produced by the Newance carpets, and detected by Todd Environmental, precipitated Carol's respiratory problems. Pappano deduces that Carol "may have had some mild underlying allergic respiratory problems that were worsened significantly by the presence of the volatile organic compounds coming from the newly installed rugs." (Defend. Exhib. H at 3.) n27 Pappano's opinion is based on the temporal relationship of Carol's symptoms to her proximity to the carpeting, and his elimination of other causal factors; Pappano ruled out an infectious cause for Carol's symptoms after reviewing Carol's history and after conducting a physical examination, and Pappano ruled out Carol's allergy to dogs and [*53] dust because Carol had not experienced symptoms when previously exposed to those allergens.

n27 Pappano testified at the in limine hearing that certain persons are predisposed to allergic reactions and that Carol Heller is one of those persons. Pappano agreed that Carol's sensitivity only causes her symptoms when she is exposed to an agent which irritates her, and only for the time of her expose to the agent. Theurkauf testified that Carol would recover within one day after leaving the house. Hence, even if plaintiffs prove liability, damages would be limited because plaintiffs' injuries ended when the carpet was removed.

Pappano's opinion as to causation, however, suffers from the same defect as Todd's opinion; namely, Pappano cites no research to support his contention that the levels of VOCs detected by Todd Environmental can and did cause the type of illness allegedly experienced by Carol. At the in limine hearing, Pappano acknowledged that he was unaware of the background levels of benzene or any [*54] of the other VOCs. In addition, Pappano conceded that he had no authority that states that 2 butoxy ethanol is an irritant and no authority as to the levels of 2 butoxy ethanol required to cause a response.

Further Pappano conducted no differential diagnosis to eliminate all other likely causes, the temporal relationship relied upon by Pappano is not supported by the record, and Pappano conducted no tests to verify that Carol was sensitive to benzene, 2 butoxy ethanol or benzene homologues. In reaching his conclusion, Pappano failed to rule out all alternative possible causes of Carol Heller's illness. The district court may exclude an opinion where (1) the expert engaged in few standard diagnostic techniques normally used to rule out alternative causes and the expert offers no explanation for why his or her opinion remains reliable, or (2) the defendant points to an alternative likely cause for plaintiffs' injuries and the expert offers no reasonable explanation why he or she nevertheless believes that the defendant's action caused the plaintiffs' injuries. See *In re Paoli*, 35 F.2d at 760 (discussing expert medical testimony). Defendant suggests that other items in the Heller [*55] home could have caused Carol's illness, such as the old carpets, the carpet remnants, the carpet pad or dander from the prior owner's pets. Pappano offers no explanation for why he believes that Carol Heller's illness was caused by the Newance carpets as opposed to those other products.

Similarly, Pappano's opinion contains the premise that all VOCs detected in the April and May, 1994 air ample tests were produced by the Newance carpeting; however, Pappano does not specifically negate the possibility that the VOCs were emitted by other materials located within the home. n28 At the in limine hearing, Pappano admitted that other sources in the home could emit benzene and 2 butoxy ethanol, and the record reveals that other items were present within the Heller home that can emit the types of VOCs detected by Todd Environmental in the April and May tests. In correspondence forwarded by Todd to Carol Heller on May 23, 1994, Todd acknowledges that the detected VOCs may have been emitted by a variety of household products. Todd states that many of the hydrocarbons found in Emily Heller's bedroom closet were common to gasoline, and that the levels of Benzene found suggest that the source [*56] of that compound was small equipment or car tanks located in the garage partially below the closet. (Defend. Exhib. M at 2.) Todd also notes that benzene is not used in the manufacture of carpeting, carpet padding, or adhesives used in the installation process. Further, Todd explains that the chlorinated hydrocarbons detected were probably off-gassed from dry cleaning, and that the 2 butoxy ethanol identified in the first sample is a common component of many household cleaners for glass, wood or plastic surfaces. (Id; Defend. Addendum Exhib. E at 110.) Defendant's expert Ronald a common cleaning agent used in such products as Windex and Fantastik. Thus, Pappano does not have good grounds for his opinion that the VOC levels detected

in the April and May, 1994 air sample tests came from the Newance rugs.

n28 Todd conducted his air sample tests in Emily's bedroom closet, which contained two types of carpeting: the white Newance carpets and a second brand that plaintiffs used in the girls' bedrooms. Carol Heller testified at the in limine hearing that the remnant covered over 60% or more of the closet floor, while the Newance carpet covered 40% or less. There is no evidence of record to link defendant to the remnant carpets in the girls' bedrooms and, consequently, plaintiffs have failed to eliminate a possible alternative source for the VOCs detected by the air sample tests.

[*57]

Additionally, there was no significant temporal relationship between Thomas and Carol's symptoms and their exposure to the odors emanating from the Newance Carpeting; plaintiffs proffer no statistical evidence to show the existence of a statistically significant correlation. Moreover, the following incidences disprove the existence of a temporal relationship: (1) although Pappano testified at the in limine hearing that individuals with VOC sensitivity would experience symptoms within 24 hours of exposure, the record reveals that the carpets were installed on December 13-14, 1993 and yet Carol did not experience symptoms until the last week in December, 1993; n29 (2) Carol and Thomas Heller claim that they continued to experience symptoms after the carpet had been removed from the Heller residence; (3) Thomas Heller received treatment for respiratory illness soon after moving into the Fox Glove home but prior to the installation of the carpets. n30

n29 Carol Heller testified at the in limine hearing that her symptoms began to appear in the last week of December, 1993. However, at her deposition, Carol testified that she started to experience symptoms in early January, 1994 after New Year's day. (Plain. Exhib. 1 at 102.) Similarly, Pappano's report states that Carol informed him that she started to experience symptoms in January, 1994. (Defend. Exhib. H at 2.) For the purpose of this motion, the court will accept Carol's testimony that her symptoms first appeared in the last week of December, 1993, i.e., after December 24, 1993. However, because the Newance carpet was installed on December 13-14, 1993, Carol's symptoms appeared over ten days after the installation.

[*58]

n30 At the in limine hearing, Pappano stated

that he treated Thomas Heller on December 9, 1993, prior to the Newance carpeting being installed. Thomas informed Pappano that he was suffering from asthmatic conditions brought on by carpet vacuuming, and Pappano concluded that Thomas' symptoms were caused by the cats which the prior owners had in the house.

Finally, Pappano did not conduct any tests to verify his conclusion that Carol's symptoms were precipitated by exposure to benzene, 2 butoxy ethanol or benzene homologues. Although Pappano conducted skin tests to ascertain whether Carol was allergic to dust and animal dander, he did not attempt to reproduce Carol's reactions by subjecting her to similar tests for low concentrations of VOCs.

Consequently, Pappano's testimony regarding causation is similarly inadmissible.

iii. Julio Amadio

Doctor Amadio testified at his deposition that he diagnosed Carol Heller's breathing difficulties as asthma, and that he determined that the cause of her illness was the new carpet. Amadio claimed that his conclusion was based on his reading of articles [*59] that set forth that there could be a direct relationship between carpets and asthma, and his observation that plaintiffs had previously installed new carpets and that Carol's asthma improve when she went out-of-doors. (Plain. Exhib. 6 at 8.)

However, at the in limine hearing, Amadio testified that he was unable to render a definite opinion with a reasonable degree of medical certainty that the Newance carpet caused Carol Heller's respiratory illness. Consequently, while Amadio's testimony is admissible with respect to his asthma diagnosis—in that Amadio observed Thomas and Carol's symptoms and he is competent to render that diagnosis—Amadio's opinion as to whether defendant's rugs caused Carol Heller's symptoms is inadmissible.

iv. Edward Theurkauf

Finally, although plaintiffs state in a reply brief that Doctor Theurkauf attributed Carol's illness to the carpets, the record reveals that Theurkauf offers no opinion as to whether the Newance carpeting caused Carol's symptoms. Rather, at the in limine hearing and at his deposition, Theurkauf merely opined that Carol Heller suffered bronchospasms caused by an environmental irritant, but that he did not know what environmental [*60] irritant was causing her bronchospasms. (Defend. Motion in limine Exhib. K at 4, 7.) Theurkauf testified that he cannot tell whether or not the Newance carpets caused Carol's illness. (Id. at 15.)

Consequently, the opinions of plaintiffs' experts regarding causation are inadmissible, and defendant's motion in limine to exclude will be granted.

C. Summary Judgment Motion

i. Defective Design and/or Manufacture, Failure to Warn: Whether a Defect in the Newance Carpets Caused Plaintiffs Injury

Absent the testimony of their experts, plaintiffs provide no admissible evidence that Carol Heller's injuries were caused by defendant's carpeting. Plaintiffs have failed to present evidence sufficient to establish general or specific causation or to show that the Newance carpets manufactured by defendant were defective. Plaintiffs' remaining evidence is the testimony of Thomas and Carol Heller that Carol experienced asthmatic symptoms when in the Fox Glove residence. However, plaintiffs offer no reasonable scientific explanation for how the carpets caused Carol's symptoms and, as stated above, the temporal relationship between Carol's illness and her proximity to defendant's [*61] rugs does not withstand scrutiny; defendant's carpeting is not the obvious cause of plaintiffs' illnesses because plaintiffs experienced symptoms before and after the carpeting was removed, and because plaintiffs have not ruled out other possible causes of their health problems. Consequently, absent proof of defect or causation, defendant is entitled to summary judgment on plaintiffs' defective design and/or manufacture claim and failure to warn claim.

With respect to plaintiffs' additional claims, defendant contends that plaintiffs have failed to proffer evidence in support of each element of their claims.

ii. Magnuson-Moss Act

Plaintiffs claim damages for breach of warranty pursuant to the Magnuson-Moss Act, 15 U.S.C. § 2310(d). However, the Magnuson Moss Act does not create a private, independent cause of action for personal injury damages arising out of a breach of warranty, absent allegations that defendant violated a specific standard set forth in the Act. See *Santarelli v. BP America*, 913 F. Supp. 324 (M.D. Pa. 1996); 15 U.S.C. 2311(b)(2) ("Nothing in this chapter (other than [substantive federal warranty standards]) shall (A) affect the liability of, or impose [*62] liability on, any person for personal injury, or (B) supersede any provision of state law regarding consequential damages for injury to the person or other injury.") Here, plaintiffs merely allege a breach of warranty. Further, a plaintiff may not maintain a Magnuson-Moss Act claim unless plaintiffs have given defendant an opportunity to cure the alleged breach of warranty. 15 U.S.C. § 2310(e). Here, there is no dispute that defendant removed the Newance carpets and refunded plaintiffs for the cost of the carpets and instal-

lation. Consequently, defendant is entitled to summary judgment on plaintiffs' Magnuson-Moss Act claim.

iii. Negligent and Intentional Misrepresentation

Plaintiffs contend that defendant misrepresented facts concerning prior complaints received by defendant regarding carpet emissions, and that plaintiffs' reliance on defendant's representations caused them to remain in the Fox Glove home for an additional three weeks, thus prolonging their suffering. According to plaintiffs, Carol Heller telephoned defendant on March 21, April 5, and April 28, 1994, seeking information to help her determine the cause of her family's illnesses. Carol Heller testifies that her [*63] calls were referred to Todd Bethel, who informed Heller that he had never heard of any complaints of persons having health problems or severe respiratory problems related to new carpets, and that the cause of her family's health problems must be attributable to something else. (Plain. Exhib. 1 at 170-74.) Plaintiffs claim that contrary to his alleged assertion, Bethel was well aware of carpet related health complaints because Bethel was the defendant employee responsible for handling customer complaints of health problems. Further, plaintiffs note that by January, 1994, 100% of Bethel's time was devoted to handling complaints related to carpet emissions. (Plain. Exhib. 48.) In addition, plaintiffs assert that defendant never sent Carol Heller any information about the health effects of the chemicals emitted from carpeting. (Plain. Exhib. 1 at 199-200.)

Under Pennsylvania law, a cause of action for fraud consists of the following elements: (1) a misrepresentation; (2) a fraudulent utterance thereof; (3) an intention by the maker that the recipient will thereby be induced to act; (4) justifiable reliance by the recipient upon the misrepresentation; (5) damage to the recipient as the [*64] proximate result. *Woodward v. Dietrich*, 378 Pa. Super. 111, 548 A.2d 301 (Pa. Super. Ct. 1988). "A 'negligent' misrepresentation is a misrepresentation which arises from a want of 'reasonable care or competence in obtaining or communicating information,' as opposed to a 'fraudulent' misrepresentation which involves either a 'knowing' or a 'reckless' communication of a misrepresentation." *Id.* at 308 n.5.

Here, a question of fact exists with respect to whether Bethel informed Carol Heller that he was not aware of other health related complaints. n31 Nevertheless, plaintiffs claim fails because there is no evidence of record to support plaintiffs' assertion that they were injured by reliance on Bethel's alleged misrepresentation. The Hellers moved out of the Fox Glove residence on April 7, 1994, and plaintiffs proffer no evidence to prove that they would have moved-out of the Fox Glove residence at an earlier date if they had been aware of the existence of other

complaints to defendant. Further, plaintiffs have not substantiated their assertion that they suffered injuries as a consequence of having dwelled in the Fox Glove home for a further three weeks.

n31 In his deposition, Bethel stated that he would not have made such a statement. (Defend. Exhib. J at 59-60.)

[*65]

iv. Pennsylvania Consumer Protection Laws

Plaintiffs claim that defendant violated the Pennsylvania Unfair Trade Practices and Consumer Protection Laws, 73 P.S. §§ 201 et seq., when it represented that its carpets passed a quality control program. Defendant places a "green tag" on all carpets it sells that pass a CRI inspection test. To qualify for a green tag, a sample from a style of carpet is tested once a year to ensure that total VOC emissions do not exceed a concentration of 0.6 mg/m³. Plaintiff claims that the green tag program is confusing to consumers and lacks credibility in that the emission results for one carpet sample are not indicative of the emissions for all the hundreds of carpets that are in the same category.

"The basic policy of the Pennsylvania Consumer Protection law is to prohibit unfair methods of competition and unfair and deceptive practices in the conduct of a trade or commerce." *Rizzo v. Michener*, 401 Pa. Super. 47, 584 A.2d 973, 980 (Pa. Super. Ct. 1990). To maintain a cause of action under the Pennsylvania Unfair Trade Practices Act, plaintiffs must show the essential elements of fraud: (1) material misrepresentation of a material fact; [*66] (2) scienter; (3) intention by the declarant to induce action; (4) justifiable reliance by the party defrauded by the misrepresentation; and (5) damages to the party defrauded as a proximate result. *Prime Meats v. Yochim*, 422 Pa. Super. 460, 619 A.2d 769 (Pa. Super. Ct. 1993). Here, plaintiffs have failed to proffer expert testimony that the Newance carpeting manufactured by defendant was defective, or that the green tag Program was confusing or deceptive. Moreover, plaintiffs did not rely on the CRI green tag representation of safety when purchasing the carpets; Carol Heller testified at her deposition that she never saw any green tags on the carpets. (Plain. Exhib. 1 at 172.) n32

n32 Similarly, to the extent that plaintiffs' complaint alleges a state law breach of warranty claim, that claim fails because plaintiffs offer no admissible evidence that the carpets in their Fox Glove home were defective. See *Altronics of Bethlehem, Inc. v. Repco*, 957 F.2d 1102, 1105 (3d Cir. 1992) (breach of warranty claim requires proof that prod-

uct was defective).

[*67]

v. Medical Monitoring

In their reply brief, plaintiffs indicate that they intend to file a motion to withdraw without prejudice their medical monitoring claim. (Plain. Reply Memo. at 64.) In response, defendant argues that the court should either dismiss that claim with prejudice or grant summary judgment because there is no evidence to support plaintiffs' medical monitoring claim.

Voluntary dismissal at this stage of the proceedings is a matter for the court's discretion. See *Sinclair v. Soniform, Inc.*, 935 F.2d 599, 603 (3d Cir. 1991); Fed. R. Civ. P. 41(a)(2) (after defendant has filed answer, "an action shall not be dismissed at the plaintiff's instance save upon order of the court and upon such terms and conditions as the court deems proper"). In deciding whether to grant a voluntary dismissal, the court may consider the following factors: (1) the excessive and duplicative expense of a second litigation; (2) the effort and expense incurred by defendant in preparing for trial; (3) the extent to which the current suit has progressed; and (4) plaintiffs' diligence in bringing the motion to dismiss. *Maleski v. DP Realty Trust*, 162 F.R.D. 496 (E.D. Pa.), remanded by [*68] *Kaiser v. DP Realty Trust*, 72 F.3d 123 (3d Cir. 1995). Because of the time and resources already expended by defendant in litigating plaintiffs' medical monitoring claim, and because plaintiffs did not move for a dismissal until after discovery and after defendant moved for summary judgment, the court will deny plaintiffs' request to withdraw their medical monitoring claim without prejudice, and will address the merits of that claim.

In Count VI of the amended complaint, plaintiffs allege that they have been exposed to chemicals known to cause an enhanced risk of contracting latent diseases, and that early and frequent medical monitoring and detection is reasonably available and necessary to protect their health.

To obtain damages for medical monitoring, plaintiffs must establish the following four elements:

1. Plaintiff was significantly exposed to a proven hazardous substance through the negligent action of the defendant.
2. As a proximate result of such exposure, plaintiff suffers a significantly increased risk of contracting a serious latent disease.
3. That increased risk makes periodic examination reasonably necessary.
4. Monitoring and testing procedures exist [*69] which make the early detection and treatment of the disease pos-

sible and beneficial.

Redland Soccer Club v. Dept. of Army of U.S., 55 F.3d 827, 845 (3d Cir. 1995), cert. denied, 133 L. Ed. 2d 725, 116 S. Ct. 772 (1996). Plaintiffs must prove that they were exposed to chemicals "beyond what would normally be encountered by a person in everyday life, so that the risk of being injured from the exposure is greater, in some way, than the normal risks all of us encounter in our everyday lives." *Id.* at 846. Additionally, plaintiffs must prove that the increased risks of harm caused by their exposure to toxic substances "warrant a change in the medical monitoring that otherwise would be prescribed for [them]." *Id.* at 846 (quotation omitted).

Here, plaintiffs have adduced no evidence that defendant's carpets emitted VOCs at concentrations harmful to health, that the levels of VOCs detected by Todd Environmental are higher than the normal background presence, that plaintiffs suffer increased risk of contracting a serious latent disease as a result of their exposure to the levels of VOCs detected by Todd Environmental,

or that medical monitoring would be beneficial [*70] to the treatment and early detection of serious latent disease. Consequently, defendant will be granted summary judgment on plaintiffs' medical monitoring claim.

III. CONCLUSION

Defendant's motion in limine to exclude expert testimony and motion for summary judgment will be granted.

An appropriate order follows.

ORDER

AND NOW, this 15th day of August, 1997, upon consideration of defendant's motion in limine to exclude expert testimony and motion for summary judgment, and the plaintiffs' responses thereto, **IT IS HEREBY ORDERED** that defendant's motions are **GRANTED**, and judgment is entered in favor of the defendant and against the plaintiffs.

BY THE COURT

William H. Yohn, Jr., Judge

TAB 4

LEXSEE 1998 U.S. Dist. LEXIS 17392

**ANGELO LAULETTA, WILLIAM ARMSTRONG, EMIDIO PALOMBI, and JAMES
RAYNOCK, Plaintiffs, v. TRANSWORLD EXPRESS, INC., and TRANSWORLD
AIRLINES, INC., Defendants.**

Civil Action No. 96-4098

**UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF
PENNSYLVANIA**

*1998 U.S. Dist. LEXIS 17392***October 29, 1998, Decided****October 30, 1998, Entered****DISPOSITION:**

[*1] Defendants' Motions to Dismiss, or in the Alternative, for Summary Judgment GRANTED as to the claim of Emidio Palombi, and DENIED as to the claims of Angelo Lauletta and William Armstrong.

the CBA. However, as the CBA did not incorporate the administration of the benefits plans that it referenced, these plaintiffs were not required to arbitrate their claims pertaining to the administration, as opposed to the termination, of their benefits. Accordingly, the court had jurisdiction under ERISA to address the administration of the group insurance plans.

CASE SUMMARY

PROCEDURAL POSTURE: Plaintiffs, a retired and two discharged employees, instituted an action against defendants, a former employer and its successor, alleging a violation of the Employee Retirement Income Security Act (ERISA) in the management of plaintiffs' group insurance plan. Defendants sought dismissal or summary judgment on the basis that the retired employee suffered no injury and that the court lacked jurisdiction over the discharged employees' claims.

OVERVIEW: As the retired employee failed to allege an actual injury and no claim for medical benefits was ever denied, the court concluded that he lacked standing. The discharged employees were terminated for failing to request an extension for leaves of absence. They sought to avoid Railway Labor Act (RLA) preemption by alleging that defendants breached their fiduciary duty in the administration of a benefits plan that existed separate and apart from the collective bargaining agreement (CBA). The court held that to the extent their complaint asserted that the termination of their benefits, concomitant with the termination of their employment, was a breach of defendants' duties under the Employee Retirement Income Security Act (ERISA), it had no jurisdiction to hear this claim as it involved the application and interpretation of

OUTCOME: The court granted defendants' motions for dismissal, or alternatively, for summary judgment, as to the claim of the retired employee. The court denied defendants' alternative motions as to the plan administration claims of the discharged employees.

CORE CONCEPTS

Civil Procedure : Pleading & Practice : Defenses, Objections & Demurrers : Motions to Dismiss

For purposes of ruling on a motion to dismiss for want of standing, the trial court must accept as true all material allegations in the complaint, and must construe the complaint in favor of the complaining party.

Civil Procedure : Justiciability : Standing
Constitutional Law : The Judiciary : Case or Controversy : Standing

The constitutional requirements to establish Article III standing are: first, the plaintiff must allege that he has suffered or imminently will suffer an injury, second, the plaintiff must allege that the injury is fairly traceable to the defendants' conduct, and third, the plaintiff must allege that a favorable federal court decision is likely to redress the injury. A plaintiff must clearly and specifically set forth facts sufficient to satisfy these Article III standing requirements.

Civil Procedure : Pleading & Practice : Defenses,

Objections & Demurrers : Motions to Dismiss

Once jurisdiction is challenged, the party asserting subject-matter jurisdiction has the burden of establishing it. Motions challenging the legal sufficiency of the words set forth within the four corners of a plaintiff's complaint are reviewed taking the allegations in the complaint as true. Motions that make a "factual" attack of subject-matter jurisdiction, that is, motions attacking the sufficiency of jurisdictional fact, are decided by considering extrinsic evidence, beyond the pleadings; a plaintiff's allegations are not controlling. Under a factual attack, however, the court is not confined to allegations in the complaint, but can consider affidavits, depositions, and testimony to resolve factual issues bearing on jurisdiction.

Labor & Employment Law : Collective Bargaining & Labor Relations : Arbitration : Enforcement***Labor & Employment Law : Collective Bargaining & Labor Relations : Arbitration : Limits******Labor & Employment Law : Collective Bargaining & Labor Relations : Federal Preemption***

The National Railroad Adjustment Board has exclusive jurisdiction over minor disputes within the meaning of the Railway Labor Act. A minor dispute involves the interpretation of an existing labor management contract, and must be resolved through arbitration in a grievance proceeding or before a system board of adjustment. 45 U.S.C.S. § 184. To demonstrate that the arbitrators—the System Board of Adjustment—have no jurisdiction over the claim, a party must provide positive assurance that the arbitration clause is not susceptible of an interpretation that covers the asserted dispute.

Labor & Employment Law : Employee Retirement Income Security Act (ERISA) : Civil Claims & Remedies***Labor & Employment Law : Employee Retirement Income Security Act (ERISA) : Federal Preemption******Labor & Employment Law : Collective Bargaining & Labor Relations : Federal Preemption***

To the extent a plaintiff's claim for disability benefits requires the interpretation or application of the collective bargaining agreement, it constitutes a minor dispute under the Railway Labor Act (RLA). Despite an express provision in the Employee Retirement Income Security Act (ERISA) allowing suits over the coverage and application of employee benefit plans to be brought in federal court, ERISA is not intended to, nor does it, preempt the mandatory arbitration provisions of the RLA.

Labor & Employment Law : Employee Retirement Income Security Act (ERISA) : Federal Preemption***Labor & Employment Law : Collective Bargaining & Labor Relations : Arbitration : Limits***

Although the duty of the employer to provide insurance is a matter for arbitration, the administration of the plan

under the Employee Retirement Income Security Act (ERISA) is within the jurisdiction of the federal court. ERISA's concern is within the elements of a plan and its administration after it has been established rather than to mandate the creation of the program.

COUNSEL:

For ANGELO LAULETTA, WILLIAM ARMSTRONG, EMIDIO PALOMBI, JAMES RAYNOCK, PLAINTIFFS: JAMES J. DEMARCO, DEMARCO AND DEMARCO, PHILADELPHIA, PA USA.

For TRANSWORLD EXPRESS, INC., TRANSWORLD AIRLINES, INC., DEFENDANTS: BARRY SIMON, SCHNADER, HARRISON, SEGAL & LEWIS, CHRISTOPHER J. MORAN, BARRY SIMON, SIMON, HIGGINS AND MORAN, P.C., SUSAN M. DI MARIA, PHILADELPHIA, PA USA.

JUDGES:

Robert S. Gawthrop, III, J.

OPINIONBY:

Robert S. Gawthrop, III

OPINION:**MEMORANDUM**

Before the court are defendants' Motions to Dismiss, or in the Alternative, for Summary Judgement. Upon the following reasoning, defendants' motion will be granted, but only in part.

Background

Plaintiffs, Angelo Lauletta, William Armstrong, and Emidio Palombi, n1 were employees of Pan Am Express ("Pan Am"). In December, 1991, Transworld Express, Inc. ("TWE") assumed all business obligations of Pan Am, and plaintiffs became employees of TWE. TWE assumed the responsibility for the administration of the employees' Group Medical and [*2] Insurance Plan, in which plaintiffs were participants. n2 That same month, TWE and the International Brotherhood of Teamsters Airline-Aerospace Employees Teamsters Local 732, entered into a collective bargaining agreement ("CBA"), which governed the terms and conditions of plaintiffs' employment. Sometime in 1995, Transworld Airlines, Inc. ("TWA") became involved in the operation of TWE.

n1 Plaintiff James Raynock has withdrawn his claims against defendants.

n2 Specifically, plaintiffs were participants in either the Group Medical Expense Plan, Group Long Term Disability Income Insurance Plan,

Group Accidental Insurance Plan, Group Life Insurance Plan, or Group Accidental Death and Dismemberment Insurance Plan.

Emidio Palombi

Mr. Palombi retired from TWE in April 1993, due to illness caused by workplace exposure to toxic chemicals. Mr. Palombi was entitled to full-paid medical insurance upon his retirement from TWE. In September 1995, Mr. Palombi was informed that on December 31, 1995, TWE would both [*3] cease operations and cease paying his medical-expense-insurance premiums. Mr. Palombi sent TWE a written objection to its plan to cease his insurance payments. On October 23, 1995, TWE informed Mr. Palombi that his medical expense premiums would be paid by TWA.

Angelo Lauletta and William Armstrong

Both Mr. Lauletta and Mr. Armstrong, who were stock clerks for TWE, became disabled from occupational exposure to toxic chemicals. Beginning in September 1992, because they felt that the exposure to toxic substances in their work area had adversely affected their health, Mr. Lauletta and Mr. Armstrong were absent from work.

On January 18, 1993, Mr. Armstrong, having exhausted all of his sick leave, went on an industrial-injury leave of absence, provided for by the CBA. On January 19, 1993, Mr. Lauletta exhausted his sick leave and went on an industrial-injury leave of absence under the terms of the CBA. The CBA provided that an employee whose leave of absence exceeded one year was required to contact TWE to request an extension.

On March 25, 1994, a TWE representative contacted Mr. Lauletta and Mr. Armstrong, individually, notifying them that they were required to request an extension [*4] of their leaves of absence. On May 5, 1994, Mr. Armstrong was sent a second letter informing him that he must submit a request for an extension of his leave of absence. Neither Mr. Lauletta nor Mr. Armstrong informed TWE of their desire to request an extension. On September 9, 1994, Mr. Armstrong and Mr. Lauletta were informed that because of their failure to comply with the CBA's requirement for requests for extensions of leaves of absence, their employment with TWE would be terminated on September 17, 1994. At the time of their termination, Mr. Lauletta and Mr. Armstrong had been on unpaid medical leave since January 1993.

Mr. Lauletta and Mr. Armstrong requested, under the terms of the CBA, that TWE hold a hearing concerning the termination of their employment. Under the CBA's grievance procedures for nondisciplinary actions, the Union investigated plaintiffs' termination and con-

cluded that TWE had not violated the CBA, and, that thus, plaintiffs had no basis upon which to file a grievance.

Procedural History

In January, 1995, Mr. Armstrong and Mr. Lauletta filed suit in the Court of Common Pleas of Philadelphia County, alleging that their termination of employment and [*5] consequent loss of benefits was improper. After removal to federal court, that suit was dismissed because the claims were "minor disputes" under the Railroad Labor Act, over which the National Railroad Adjustment Board has exclusive jurisdiction.

In June, 1996, Mr. Armstrong and Mr. Lauletta, joined by Mr. Palombi and another former TWE employee, Mr. Raynock, brought suit in federal court, alleging defendants' violation of ERISA in their management of plaintiffs' group insurance plans. n3 Specifically, plaintiffs claim that TWE failed to fund the medical-insurance benefits of retired employees, to process medical and disability benefit claims, to maintain medical-insurance policies, and to permit disabled employees to continue life and accident insurance.

n3 Plaintiffs' initial complaint also included class action allegations that plaintiffs have since been abandoned.

Defendants moved to dismiss plaintiffs' complaint based on the doctrine of res judicata, failure to state a claim, and lack of subject-matter [*6] jurisdiction. I dismissed plaintiffs' complaint, for lack of subject-matter jurisdiction, finding that "plaintiffs' claims rest on purported violations by the defendants of the terms of the collective bargaining agreement and not of the fiduciary duties imposed by ERISA." Defendants moved for reconsideration and were granted leave to amend their complaint "if they in good faith [could] allege that the parties did not intend the collective bargaining agreement to cover the benefits plan." Plaintiffs then filed an amended complaint, asserting identical claims, and alleging that:

The Group Medical Expense Plan described above exists separate and apart from the collective bargaining agreement between the plaintiffs' union and defendants.

Amended Compl. at P 40. Defendants now move for dismissal of, or summary judgment on, plaintiffs' amended complaint on the grounds that Mr. Palombi has failed to allege any actual injury and that, because Mr. Lauletta and Mr. Armstrong have not demonstrated that the benefits plan was intended to remain outside the scope of the collective bargaining agreement, this court lacks subject-matter jurisdiction over their claims. n4

n4 Mr. Raynock's claims have been withdrawn. Appendix to the Memorandum in Support of Defendants' Motion to Dismiss, or in the Alternative for Summary Judgment, as to the Claim of Angelo Lauletta, Ex. A.

[*7]

Discussion

Emidio Palombi

Defendants argue that, because he has failed to allege any actual injury, Mr. Palombi lacks standing to sue. "For purposes of ruling on a motion to dismiss for want of standing, ... the trial court ... must accept as true all material allegations in the complaint, and must construe the complaint in favor of the complaining party." *Warth v. Seldin*, 422 U.S. 490, 501, 45 L. Ed. 2d 343, 95 S. Ct. 2197 (1975).

The constitutional requirements to establish Article III standing are: first, the plaintiff must allege that he has suffered or imminently will suffer an injury, second, the plaintiff must allege that the injury is fairly traceable to the defendants' conduct, and third, the plaintiff must allege that a favorable federal court decision is likely to redress the injury. See *Northeastern Florida Contractors v. Jacksonville*, 508 U.S. 656, 663-64, 124 L. Ed. 2d 586, 113 S. Ct. 2297 (1993); see also *Warth*, 422 U.S. at 490. A plaintiff must "clearly and specifically set forth facts sufficient to satisfy these Article III standing requirements." *Warth*, 422 U.S. at 490.

Defendants argue that Mr. Palombi has failed to meet the first [*8] prong of the standing analysis in that he has no monetary damages and has never even had a claim for medical benefits denied. Defs' Mot. at 9. I agree that Mr. Palombi has failed to allege an "actual injury." Mr. Palombi describes his claim as a hypothetical replete with contingencies. n5 The court must accept plaintiff's allegations as true for purposes of this motion. Plaintiff is entitled to the benefit of all reasonable inferences, but not to the benefit of rank conjecture. I thus cannot assume that what plaintiff fears may happen in the future will actually come to fruition. See e.g., *Robinson v. Vaughn*, 1992 U.S. Dist. LEXIS 19518, No. 91-7646, 1992 WL 368461, at *2 (E.D. Pa. Dec. 2, 1992) (holding that plaintiff's "constant fear" of possible future injuries based on exposure to asbestos were insufficient to allege an actual injury). At this time, plaintiff has admittedly not been denied any claim for benefits and has stated that he is happy with his coverage.

n5 Mr. Palombi's concerns are couched in somewhat circuitous hypotheses:

If indeed, TWE does cease business after transferred its assets which is its announced intention, there is no entity which has properly assumed the obligations unless TWA, who has absorbed the assets either effectively assumes liability is held liable based on the fact that it has acquired TWE's assets which should have insured Mr. Palombi's benefits.

Defs.' Br. at 3.

[*9]

Because I find that Mr. Palombi lacks standing, defendants' motion to dismiss his claim shall be granted.

William Armstrong and Angelo Lauletta

Defendants argue that this court lacks subject-matter jurisdiction over the claims of Mr. Armstrong and Mr. Lauletta. n6 Plaintiffs contend federal jurisdiction exists under the Employee Retirement Income Security Act ("ERISA"), 29 U.S.C. § 1132, because the Group Medical Plan was meant to be administered independently from the collective bargaining agreement. Defendants counter that "the record developed through discovery is replete with evidence that plaintiff's claims are not separate and apart from the collective bargaining agreement." Defs.' Br. at 8 (emphasis in original).

n6 Defendants filed separate motions to dismiss, or in the alternative, summary judgment, against Mr. Armstrong and Mr. Lauletta. However, because the defendants' arguments are the same in each motion, I shall address the motions together and, in the interest of typographic economy, cite only to Mr. Lauletta's brief, unless otherwise indicated.

[*10]

Once jurisdiction is challenged, the party asserting subject-matter jurisdiction has the burden of establishing it. Motions challenging the legal sufficiency of the words set forth within the four corners of a plaintiff's complaint are reviewed taking the allegations in the complaint as true. *Mortensen v. First Federal Savings and Loan Assoc.*, 549 F.2d 884, 891 (3d Cir. 1977); see also *Lauletta v. Transworld Express, Inc.*, 1997 U.S. Dist. LEXIS 437, No. 96-4098, 1997 WL 27153, at *2 (E.D. Pa. Jan. 15, 1997). Motions that make a "factual" attack of subject-matter jurisdiction, that is, motions attacking the sufficiency of jurisdictional fact, are decided by considering extrinsic evidence, beyond the pleadings; a plaintiff's allegations are not controlling. *International Ass'n of Machinists and Aerospace Workers v. Northwest Airlines, Inc.*, 673 F.2d 700, 711 (3d Cir. 1982); see also *Gotha v. United States*, 36 V.I. 392, 115 F.3d 176, 179 (3d Cir.1997) (Under a

factual attack, however, the court is not "confined to allegations in the ... complaint, but [can] consider affidavits, depositions, and testimony to resolve factual issues bearing on jurisdiction."). Defendants here lodge a factual attack [*11] as to this court's jurisdiction over plaintiffs' amended complaint. Accordingly, I shall consider extrinsic evidence in deciding the present motion.

The National Railroad Adjustment Board ("NRAB") has exclusive jurisdiction over minor disputes within the meaning of the RLA. n7 See *Hawaiian Airlines, Inc. v. Norris*, 512 U.S. 246, 252-53, 129 L. Ed. 2d 203, 114 S. Ct. 2239 (1994) (citations omitted). "A minor dispute ... involves the interpretation of an existing labor management contract," n8 *Bonin v. American Airlines, Inc.*, 621 F.2d 635, 637 (5th Cir. 1980), and must be resolved through arbitration in a grievance proceeding or before a system board of adjustment. 45 U.S.C. § 184. To demonstrate that the arbitrators—the System Board of Adjustment—have no jurisdiction over the claim, a party must provide positive assurance that the arbitration clause is not susceptible of an interpretation that covers the asserted dispute. *Airline Pilots Assoc. Intl. v. Delta Air Lines, Inc.*, 274 U.S. App. D.C. 181, 863 F.2d 87, 93-94 (D.C. Cir. 1988). n9

n7 "Major" disputes are those concerning the formation or modification of collective bargaining agreements. "Minor" disputes cover those more-or-less routine employee grievances that arise daily within the railway industry. *Union Pac. R.R. v. Sheehan*, 439 U.S. 89, 94, 58 L. Ed. 2d 354, 99 S. Ct. 399 (1978) (per curiam).

[*12]

n8 Under the CBA at issue here, the System Board of Adjustment "shall have jurisdiction only over disputes between the Company and the Union or any employee or employees governed by this Agreement, growing out of grievances involving the interpretation or application of this agreement." CBA, Article XVII.

n9 Arbitration may be compelled only over those issues that parties have agreed by contract to arbitrate. *International Assoc. of Machinists and Aerospace Workers, Dist. No. 10 v. Waukesha Engine Division, Dresser Industries, Inc.*, 17 F.3d 196, 198 (7th Cir. 1994).

Thus, if plaintiffs' claims can be characterized as "minor disputes," the administrative remedy provided by the Railway Labor Act would be the plaintiff's exclusive remedy, depriving this court of subject-matter jurisdiction. To the extent plaintiffs' "claim for disability benefits requires

the interpretation or application of the collective bargaining agreement," it constitutes a "minor dispute under the [RLA]." *Bowe v. Northwest Airlines, Inc.*, 974 F.2d 101, 103 (8th Cir. 1992); see also *Bonin*, 621 F.2d at 638 [*13] ("Despite [ERISA's] express provision allowing suits over the coverage and application of [employee benefit] plans to be brought in federal court, ERISA was not intended to, nor did it, preempt the mandatory arbitration provisions of the Railway Labor Act.").

The RLA's mechanism for resolving minor disputes does not, however, preempt causes of action to enforce rights that are independent of the collective bargaining agreement. See *Bonin*, 621 F.2d at 639; *RCA Corp. v. Local 241, International Fed. of Prof. & Tech. Engineers*, 700 F.2d 921, 927 (3d Cir. 1983) ("the mere mentioning of the Retirement Plan in the General Agreement is insufficient reason to construe the Retirement Plan as part and parcel of the General Agreement."); *Printing Specialties, Local 680 v. Nabisco Brands, Inc.*, 833 F.2d 102, 105 (7th Cir. 1987) ("passing reference to the Pension Plan does not bring specific pension disputes ... under the umbrella of the arbitration clause of the agreement."). However, at least one court has held that a benefits plan was arguably maintained under the terms of a collective bargaining agreement, divesting the court of jurisdiction. See *Airline Pilots*, 863 F.2d [*14] at 95 (holding that the CBA "literally incorporated the terms relating to disability benefits" at issue.). n10

n10 Whether these various courts had jurisdiction, inasmuch as the plaintiffs' claims were not covered by the collective bargaining agreement, was determined by looking at the specific terms of the agreement at issue. In *Bonin*, for example, the court noted that the pension plan explicitly provided that "neither the interpretation of the Plan nor its administration shall as such be within the jurisdiction" of the collective bargaining agreement. *Bonin*, 621 F.2d at 639. In contrast, in determining that the district court lacked jurisdiction, the *Airline Pilots* court found it significant that the collective bargaining agreement specifically incorporated by reference the benefits plans at issue. *Airline Pilots*, 863 F.2d at 94.

Plaintiffs here seek to avoid RLA preemption by alleging that defendants breached their fiduciary duty in the administration of a benefits plan that exists separate [*15] and apart from the CBA. However, neither party here has pointed to any provision in the CBA that resolves whether the parties intended to separate, or to incorporate, the benefits plan within the ambit of the CBA. To glean the parties' intent, I must thus look elsewhere.

Defendants' motion points to various provisions in the CBA referring to the benefits plan, the most relevant being the provision entitled "Insurance:"

During the term of this Agreement, the Company will not reduce the Health and Welfare insurance benefits now provided without consulting with the Union in advance. Employees hereunder shall bear a proportionate share of any increases in the premiums, and benefit proportionately from any premium reduction. Employees who presently are not required to co-pay insurance premiums shall continue to be exempt from the payment of premiums during the term of this Agreement.

CBA at 43. Defendants cite to other CBA provisions, relating to: life and disability insurance for injuries from bomb explosions; group health and life insurance plans for part-time employees; including a formula to calculate premiums due; a Tuition Refund plan; and an improved vesting schedule [*16] for TWE-sponsored Retirement and Savings Plan. In addition to the CBA itself, defendants support their contention that the plans are covered by the CBA by pointing to the facts that TWE submitted proposed modifications of its benefits plans to the Union for review and approval, and that both Mr. Armstrong and Mr. Lauletta stated, at their depositions, that they believed that their claims for benefits would be appropriately addressed by filing a grievance with the System Board of Adjustment.

Mr. Armstrong and Mr. Lauletta counter that their rights arise from the insurance policies for which they paid premiums and are not dependent upon their rights under the labor agreement. n11 For example, Mr. Lauletta states that his "substantive allegations include only facts relating to his loss of accrued monthly disability benefits arising from defendant's failure to process his claim in accordance with the procedures established in the plan documents." Pls.' Br. at 2.

n11 Plaintiffs allege that defendants failed to process their vested disability benefits under the individual policies paid for by them. Specifically, plaintiffs state:

this case does not involve any opposition to either termination of on-going medical coverage or termination of business operations by TWE. [Their] substantive allegations include only facts relating to his loss of accrued monthly disability benefits arising from defendants' failure to process [their] claim in accordance with the procedure established in the plan documents. Plaintiffs Angelo Lauletta and William Armstrong also allege that their rights to continued coverage under the premium waiver provisions of their life and accident policies were

also forfeited by defendants' failure to process their claims.

Pl.'s Br. at 2.

[*17]

The legality of the termination of their employment, and with it the termination of medical and disability benefits, clearly involves the application and interpretation of the CBA. n12 The termination of a benefits plan governed by ERISA does not turn on questions of fiduciary duty, but, rather, of contractual interpretation – here, the interpretation of a collective bargaining agreement. See *American Flint Glass Workers v. Beaumont Glass Co.*, 62 F.3d 574, 579 (3d Cir. 1995). To the extent that plaintiffs' complaint asserts that the termination of their benefits, concomitant with the termination of their employment, was a breach of defendants' duties under ERISA, I find that I do not have jurisdiction to hear this claim.

n12 In fact, this appears to be the argument upon which the previous dismissals of plaintiffs' complaint were based.

To the extent that plaintiffs' claims pertain to how their monthly disability benefits were administered and whether their premium provisions were waived, these issues are [*18] not explicitly covered by the CBA. Although the CBA refers to the plan in various sections, none indicates that the parties intended the administration of the plan to be part of the CBA, and thus subject to arbitration. n13 Provisions relating to reduction of benefits, insurance for bomb explosions, insurance for part-time employees, tuition refunds and a retirement and savings plan do not necessarily extend the applicability of the CBA to plaintiffs' claims relating to the administration of the group health plan. Further, plaintiffs' mistaken belief that their benefits claims could be adequately addressed through a grievance under the CBA should not preclude them from later discovering, and asserting, their alternative remedies.

n13 Although not cited by either party, Defendant's Exhibit Armstrong 21, attached as part of Exhibit B to Defendants' Motion as to Mr. Palombi and Mr. Armstrong, tends to show that plaintiffs' claims are not covered by the CBA, at least in part. In response to plaintiffs' claim for continuation of benefits, a letter on Transworld Express letterhead, entitled "Second Level Response to first appeal ... (Lauletta/Armstrong)," states that "there is no provision in the Collective Bargaining Agreement (CBA) on the issue of benefits continuation."

[*19]

Although the duty of the employer to provide insurance is a matter for arbitration, the administration of the plan under ERISA is within the jurisdiction of this court. *Viggiano v. Shenango China Division of Anchor Hocking*, 750 F.2d 276, 281 (3d Cir. 1984) ("ERISA's concern is within the elements of a plan and its administration after it has been established rather than to mandate the creation of the program.") I thus find, based on the evidence submitted in conjunction with this motion, that the CBA does not incorporate the administration of the benefits plans that it references. Accordingly, plaintiffs need not arbitrate their claims pertaining to the administration, as opposed to the termination, of their benefits.

Because plaintiffs specifically limit their claims to the alleged improper administration of their benefits plans, defendants' motion to dismiss plaintiffs' complaint, as to Mr. Lauletta and Mr. Armstrong, will be denied. n14

n14 Defendants move, in the alternative, for

summary judgment. They have, however, not argued the merits of plaintiffs' claims, nor submitted evidence demonstrating their entitlement to judgment. Indeed, neither party here addresses the specifics of plaintiffs' claims of maladministration of the benefits plan.

[*20]

ORDER

AND NOW this 29th day of October, 1998, Defendants' Motions to Dismiss, or in the Alternative, for Summary Judgment are GRANTED as to the claim of Emidio Palombi, and DENIED as to the claims of Angelo Lauletta and William Armstrong. As to Messrs. Lauletta and Armstrong, the sole extant issue before the court is whether the defendants improperly administered the surviving plaintiffs' benefits plan.

BY THE COURT:

Robert S. Gawthrop, III J.

TAB 5

H

Only the Westlaw citation is currently available.

Superior Court of Pennsylvania.

Adelaide L. LENNON, a Minor Child By and Through Her
Mother and Natural
Guardian Susanne E. Lennon and Susanne E. Lennon in Her
Own Right, Appellants

v.

WYETH-AYERST LABORATORIES, INC., American
Home Products Corporation, Appellees

No. 1793 EDA 2000.

June 14, 2001.

Appeal from the Order Entered June 2, 2000. In the Court of
Common Pleas of Delaware County, Civil No. 99-13101.

BEFORE: MONTEMURO, [FN*] BECK, and KELLY, JJ.

[FN* Retired Justice assigned to Superior Court.

MEMORANDUM: [FN**]

[FN** This decision was reached prior to the
expiration of Justice Montemuro's assignment to
the Superior Court of Pennsylvania.

*1 This is an appeal from an order sustaining the
preliminary objections of Appellees, the defendants in a
purported class action to recover damages for economic
injury.

Appellants in this matter are a mother and her minor child.
The latter received two doses of the oral vaccine Rotashield,
designed to prevent rotavirus, a pernicious disease
responsible for significant infant mortality worldwide. The
vaccine was recalled when a possible link was discovered
between the medication and intussusception, a bowel
obstruction. It is not alleged that the child developed either
the adverse reaction to the vaccine, or the disease the
vaccine was designed to combat. Rather, Appellants seek
to recover for themselves [FN1] and all American recipients of
the vaccine, any expenditures for inoculation.

[FN1. We note that counsel of record includes the
father of the minor Appellant.

To that end, a complaint was filed alleging violations of the
Unfair Trade Practices and Consumer Protection Law,
(UTCPL) 73 Pa.C.S. § 201-1, *et seq.*, breaches of contract
and of warranty, as well as unjust enrichment and Appellees'
failure to warn. Preliminary objections were successfully

filed, and Appellants submitted an amended complaint,
which was countered by another set of preliminary
objections. After numerous responses and replies from both
sides, the trial court sustained the preliminary objections,
and this appeal followed, [FN2] raising six issues which we
address *seriatim*, although not in the order presented.

[FN2. Although the trial court failed to dismiss the
complaint in its order, Appellants are effectively
out of court. Therefore, we will treat as final an
order clearly intended to be final. See *Murphy v.*
Murphy, 599 A.2d 647, 650 (Pa.Super.1991),
appeal denied, 606 A.2d 902 (Pa.1992).

Where a preliminary objection in the nature of a demurrer
is sustained, an appellate court's review is limited. All
material set forth in the complaint as well as all inferences
reasonably deducible therefrom are admitted as true for
the purpose of review. The question presented by
demurrer is whether, on the facts averred, the law says
with certainty that no recovery is possible. Where a doubt
exists as to whether a demurrer should be sustained, the
doubt should be resolved in favor of overruling it.

Moser v. Heistand, 681 A.2d 1322, 1325 (Pa.1996).
Moreover, "[w]e need not accept a party's allegations as true
to the extent they constitute conclusions of law." *Fay v. Erie*
Insurance Group, 723 A.2d 712, 714 (Pa.Super.1999).

Appellants first question the trial court's determination that
their claim of breach of an implied warranty of
merchantability by Appellees as to the vaccine is barred by
the learned intermediary doctrine. Under this principle, the
manufacturer of a drug has a duty to warn only the
prescribing physician, *i.e.*, the learned intermediary and not
the patient, of any known adverse reactions to the drug.
Incollingo v. Ewing, 282 A.2d 206, 220 (Pa.1971);
Makripodis v. Merrell-Dow Pharmaceuticals, Inc., 523
A.2d 374, 377 (Pa.Super.1987). Appellants argue that the
doctrine is inapplicable here because the warning given to
physicians was inadequate, and because the marketing of
pharmaceutical products directly to the public has
invalidated the learned intermediary doctrine. We are
unpersuaded.

*2 To address these arguments in reverse order, the learned
intermediary rule exists specifically because certain drugs
are available only upon prescription, which only a licensed
physician may provide, or, as in the case of the vaccine,
upon administration by a health care professional at a
doctor's direction. *Id.* Media dissemination of information
concerning the existence of these drugs does not enhance
the public's ability to acquire them, as the skill and
knowledge of the physician still must be brought to bear in a
determination of whether the pharmaceutical is appropriate
to the condition of the patient. Thus, the learned

intermediary still stands between the advertisement and public consumption of the product. Appellants claim that the learned intermediary doctrine has become anachronistic, and should therefore fall.

As to Appellants' assertion that the warning was inadequate, our Supreme Court has repeatedly stated that "where the adequacy of warnings associated with prescription drugs is at issue, the failure of the manufacturer to exercise reasonable care to warn of dangers, i.e., the manufacturer's negligence, is the only recognized basis of liability." *Hahn v. Richter*, 673 A.2d 888, 891 (Pa.1996) (citing *Incollingo v. Ewing*, 282 A.2d 206 (Pa.1971) and *Baldino v. Castagna*, 478 A.2d 807 (Pa.1984) (emphasis added)). It has also been long settled that "no cause of action exists for negligence that causes only economic loss." *Aikens v. Baltimore and Ohio Railroad Company*, 501 A.2d 277, 279 (Pa.Super.1985); see also *Ellenbogen v. PNC Bank, N.A.*, 731 A.2d 175, 188 n. 26 (Pa.Super.1999); *General Public Utilities v. Glass Kitchens of Lancaster, Inc.*, 542 A.2d 567, 570 (Pa.Super.1988). The Complaint contains no allegation that the child suffered personal injury, only that Appellants sustained economic harm. Thus the trial court properly found that Appellants had stated no claim on which relief could be granted as to Appellees' alleged failure to warn, and preliminary objections were justifiably sustained.

Appellants next [FN3] argue that they have, despite the trial court's decision to the contrary, stated claims under the UTPCPL, as well as for breach of contract, breach of warranty, negligent misrepresentation, unjust enrichment and declaratory judgment. To take these in turn, "[t]he general purpose of the UTPCPL is to protect the public from fraud and unfair or deceptive business practices." *Burke v. Yingling*, 666 A.2d 288, 291 (Pa.Super.1995). The section of the statute under which this action is brought provides as follows:

FN3. Appellants' second issue is that the trial court erred in its determination that they did not adequately plead damages. Although presented separately, this claim is actually a component and will be addressed in the context of the issues to which it relates.

Any person who purchases or leases goods or services primarily for personal, family or household purposes and thereby suffers any ascertainable loss of money or property, real or personal, as a result of the employment by any person of the method, act or practice declared unlawful by section 3 of this act, may bring a private action to recover actual damages or one hundred dollars (\$100), whichever is greater....

*3 73 P.S. § 201-9.2(a).

First, and most critically, Appellants have failed to advance

the necessary precondition that their alleged damages are the product of any action by Appellees. *DiLucido v. Terminix International, Inc.*, 676 A.2d 1237, 1240 (Pa.Super.1996), appeal denied, 684 A.2d 557 (Pa.1996). Like the appellants in *DiLucido*, Appellants herein do quite the opposite, stating that they "unwittingly paid for the Rotashield vaccine which they would not have done had the true facts been known." (Amended Complaint at 12). Moreover, in presenting their action under the statute, Appellants fail to assert ascertainable damages. The only such statement occurs elsewhere in the Complaint, and reads as follows: "Susanne Lennon made payment through her medical insurance, as well as directly and personally through co-payments for the administration of the vaccine ." (*Id.* at 2). The trial court notes that no claim has been made that the insurance co-pay was any higher when the vaccine was administered than it would have been otherwise.

Accordingly, this court is left to guess as to whether said co-pay was a standard fee based on insurance rate-making for a bundle of services typically rendered during an infant check-up or whether it was a real tangible out-of-pocket expense incurred by plaintiff to effectively purchase the Rotashield vaccine.

(Trial Ct. Op. at 19). Since Appellants fail to assert ascertainable damages, this issue is meritless.

Appellants further complain that the trial court failed to determine whether the UTPCPL applies to prescription drugs and vaccines. This claim is similarly without merit. As the foregoing explanation describes, the trial court properly found that Appellants' attempt to state a cause of action under this legislation was both factually and legally deficient. Therefore, even if vaccines are covered by the provisions of the UTPCPL, Appellants have failed to comply with the requirements for advancing a compensable claim.

Next Appellants argue that they have stated a claim for breach of contract based on their agreement to pay for the vaccine either personally or through insurance coverage. Appellants correctly state that "[a] cause of action for breach of contract must be established by pleading (1) the existence of a contract, including its essential terms, (2) a breach of duty imposed by the contract and (3) resultant damages." *Corestates Bank, N.A. v. Cutillo*, 723 A.2d 1053, 1058 (Pa.Super.1999). "While not every term of a contract must be stated in complete detail, every element must be specifically pleaded." *Id.*

However, "[t]he consideration necessary to establish a valid contract, express or implied in fact, must be an act, a forbearance, or a return promise, bargained for and given in exchange for the promise." *Thomas v. R.J. Reynolds Tobacco Co.*, 38 A.2d 61, 63 (Pa.1944). As the trial court observes, no facts are alleged which support the assertion

that a contract existed. In their Complaint, Appellants state only that a contract was formed by their agreement to pay for the Rotashield vaccine. As noted above, allegations which constitute conclusions of law, need not be accepted as true. *Fay v. Erie Insurance Group*, *supra*. We join the trial court in declining to do so here.

*4 Appellants further contend that "[a]n implied term or covenant of defendants' contract with plaintiffs and the Class was that Rotashield was safe for its intended use and possessed the characteristics, benefits, qualities and advantages represented by defendants." (Amended Complaint at 12). As the trial court correctly points out, this language merely reiterates Appellants' claim of breach of an implied warranty of merchantability. As we have already determined, such a claim is barred by the learned intermediary rule.

Appellants next defend their assertion of a claim for negligent misrepresentation. The criteria for such an action are "(1) a misrepresentation of a material fact; (2) made under circumstances in which the misrepresenter ought to have known its falsity; (3) with an intent to induce another to act on it; and, (4) which results in injury to a party acting in justifiable reliance on the misrepresentation." *Bortz v. Noon*, 729 A.2d 555, 561 (Pa.1999). These elements make clear, as does the very name of the cause of action, that this is a negligence claim. As we have explained above, negligence actions do not lie for injuries which are solely economic. *Aikens*, *supra*.

Next, Appellants challenge the trial court's dismissal of their claim for unjust enrichment.

Unjust enrichment is a quasi-contractual doctrine based in equity; its elements include benefits conferred on defendant by plaintiff, and acceptance and retention of such benefits under such circumstances that it would be inequitable for defendant to retain the benefit without payment of value. When considering the validity of a claim for unjust enrichment, we must focus on whether the enrichment of the defendant is *unjust*. The doctrine does not apply simply because the defendant may have benefited as a result of the actions of plaintiff.

Wiernik v. PHH U.S. Mortgage Corp., 736 A.2d 616, 622 (Pa.Super.1999), *appeal denied*, 751 A.2d 193 (Pa.1999) (citations omitted) (emphasis in original).

We return once more to Appellants' failure to demonstrate that the insurance co-pay which they advance as the basis for this claim was any different than it would have been had the child not been vaccinated, and our conclusion remains the same. Appellants have not demonstrated the injustice of Appellees' receipt of payments which have themselves remained unproven *qua* payment. [FN4]

FN4. Appellants argue that Pa.R.C.P. 1021(a)

prohibits inclusion of a specific sum in any pleading demanding relief for unliquidated damages. However, again, they fail to distinguish in any way between co-payments normally expended for an office visit when the vaccine was not administered, and the increases, if any, attributable to the vaccine.

Appellants insist, contrary to the trial court's finding that their request for declaratory relief is a repleading of their other claims, that they have indeed stated a valid claim for declaratory relief. 42 Pa.C.S.A. § 7532 provides in pertinent part that "Courts of record ... shall have power to declare rights, status and other legal relations whether or not further relief is or could be claimed."

In their Complaint, the count which contains the request for a declaratory judgment first incorporates the previous paragraphs of the pleading, and then announces without further preamble that Appellants are entitled to a declaratory judgement. They then demand an order permitting the suit to be maintained as a class action, declaring Appellees' conduct violative of the "applicable provisions of Pennsylvania law," (Amended Complaint at 18), and Appellees liable to pay remuneration. The trial court found, correctly and inevitably, that this count merely reiterated Appellants' previous claims.

*5 Appellants' penultimate contention is that they have stated a viable claim for punitive damages. However, "[a] request for punitive damages does not constitute a cause of action in and of itself. Rather, a request for punitive damages is merely incidental to a cause of action." *Feingold v. SEPTA*, 517 A.2d 1270, 1276 (Pa.1986). Appellants' reliance on *McDaniel v. Merck, Sharp & Dohme*, 533 A.2d 436 (Pa.Super.1987), to support the proposition that a punitive damages claim may be advanced, is misplaced. There punitive damages were requested, that is, claimed, in connection with a cause of action sounding in negligence; they were not separate from the substance of the suit. A punitive damages claim was permitted as to one defendant against which the appellant had "alleged misconduct ... beyond that conduct required in the underlying strict liability claim." *Id.* No such indivisibility exists here; no discrete claim underlies Appellants' demand for punitive damages.

Appellants' remaining issue asserts that they should have been granted leave by the court to file a second amended complaint to address any pleading deficiencies found by the court. Although amendment of pleadings is to be liberally allowed absent an error of law or resulting prejudice to the opposing party, *Werner v. Zazyczny*, 681 A.2d 1331, 1338 (Pa.1996), Pa.R.C.P. 1033 requires that a party may amend a pleading "by filed consent of an adverse party or by leave

of court." Indeed, a pleading filed in the absence of such consent is a nullity. *Catanese v. Taormina*, 263 A.2d 372, 374 (Pa.1970). Moreover, a court is not required to allow or order amendment *sua sponte*, or where the party involved will be unable to state a claim on which relief could be granted. *Werner, supra*. Appellants failed to make the necessary request for amendment. [FN5]

FN5. We note that in *Binswanger v. Levy*, 457 A.2d 103, 106 (Pa.Super.1983), cited by Appellants for the proposition that "plaintiffs do not waive the right to amend the complaint to set forth additional theories, even after the order [sustaining preliminary objections] was affirmed on appeal," (Appellant's Brief at 42), the appellants, unlike Appellants herein, requested permission to make amendments.

Order affirmed.

2001 WL 755944, 2001 WL 755944 (Pa.Super.)

END OF DOCUMENT

TAB 6

3 of 7 DOCUMENTS

**IN RE: PAOLI RAILROAD YARD PCB LITIGATION. THIS DOCUMENT RELATES
TO Narcise v. SEPTA, et al., Williams v. SEPTA, et al., Stanbach v. SEPTA, et al.**

MASTER FILE NO. 86-2229, No. 87-1190, No. 87-1258, No. 87-3227

**UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF
PENNSYLVANIA**

2000 U.S. Dist. LEXIS 2529

March 7, 2000, Decided

March 8, 2000, Filed

PRIOR HISTORY:

[*1] Original Opinion of October 21, 1992, Reported at: 1992 U.S. Dist. LEXIS 18433; 1992 U.S. Dist. LEXIS 18430.

DISPOSITION:

Plaintiffs' Motion for Reconsideration GRANTED in part and DENIED in part.

CASE SUMMARY

PROCEDURAL POSTURE: Plaintiffs filed a motion for reconsideration of the court's order excluding the testimony of plaintiff's expert witnesses.

OVERVIEW: Plaintiffs initially filed an action alleging that they had suffered from a variety of severe and unusual illnesses as a result of their exposure to polychlorinated biphenyls, used in the transformers of train cars which the plaintiffs serviced and maintained in the Paoli Railroad Yard. Plaintiffs filed a motion for reconsideration of the instant court's order excluding the testimony of plaintiff's expert witnesses. The court held that neither the "substantial factor" test under common law nor the Federal Employers' Liability Act ("FELA"), 45 U.S.C.S. § 51, standard of causation lowered the burden of admissibility with respect to expert testimony. The court further held that one doctor's opinions regarding bodily injury would be excluded, where the doctor failed to explain on a plaintiff-by-plaintiff, disease-by-disease basis why her opinion is reliable and why she ruled out alternative causes.

OUTCOME: Plaintiffs' motion for reconsideration of order excluding medical witnesses' testimony granted in part and denied in part. One doctor's testimony regarding personal injury opinions and medical monitoring opinion was denied. The second doctor's testimony was denied only as to his recalculation of American Medical Laboratory tests and his back calculations.

CORE CONCEPTS

Civil Procedure : Relief From Judgment

The purpose of a motion of reconsideration is to correct manifest errors of law or fact or to present newly discovered evidence. Accordingly, a district court will grant a party's motion for reconsideration in any of three situations: (1) the availability of new evidence not previously available, (2) an intervening change in controlling law, or (3) the need to correct a clear error of law or to prevent manifest injustice.

Torts : Causation

Even under the substantial factor test, plaintiffs must prove that defendants' actions were a cause of plaintiffs' injuries before the burden switches to defendant to show that the injuries would have occurred even absent any action by the defendant.

Evidence : Witnesses : Expert Testimony

Torts : Causation

If the medical expert's opinion on causation has a factual basis and supporting scientific theory that is reliable, it should be admitted. However, where a defendant points to a plausible alternative cause and the doctor offers no explanation for why he or she has concluded that was not the sole cause, that doctor's methodology is unreliable.

Evidence : Witnesses : Expert Testimony

If drawing a particular conclusion requires specialized knowledge, expert testimony is required.

Evidence : Witnesses : Expert Testimony

Like the "substantial factor" standard, the Federal Employers' Liability Act, 45 U.S.C.S. § 51, causation standard does not lower the burden of admissibility.

Evidence : Witnesses : Expert Testimony

In reviewing the reliability of a physician's testimony the Third Circuit has stated the following: Performance of physical examinations, taking of medical histories, and employment of reliable laboratory tests all provide significant evidence of a reliable differential diagnosis, and their absence makes it much less likely that a differential diagnosis is reliable. Sometimes differential diagnosis can be reliable with less than full information.

Evidence : Witnesses : Expert Testimony

In reviewing the reliability of a physician's testimony the Third Circuit has stated the following: A physician who evaluates a patient in preparation for litigation should seek more than a patient's self-report of symptoms or illness and hence should either examine the patient or review the patient's medical records simply in order to determine that a patient is ill and what illness the patient has contracted.

Evidence : Witnesses : Expert Testimony

In reviewing the reliability of a physician's testimony the Third Circuit has stated the following: Evaluation of the patient's medical records, like performance of a physical examination, is a reliable method of concluding that a patient is ill even in the absence of a physical examination. Generally, a doctor only needs one reliable source of information showing that the plaintiff is ill and either a physical examination or medical records will suffice — but the doctor does need at least one of these sources.

Evidence : Witnesses : Expert Testimony

In reviewing the reliability of a physician's testimony the Third Circuit has stated the following: Where physicians engaged in few of the standard procedures of differential diagnosis, they had to offer a good explanation as to why their conclusion remained reliable. Where they did employ such standard techniques, they still had to offer such an explanation if the defendants pointed to some likely cause of the plaintiff's illness other than the defendants' actions.

Evidence : Witnesses : Expert Testimony

The opinion of a doctor who has engaged in few standard diagnostic techniques should be excluded unless the doctor offers a good justification for his or her conclusion.

Evidence : Witnesses : Expert Testimony

Even under Federal Employers' Liability Act, 45 U.S.C.S. § 51, to render an admissible opinion, a medical expert must be able to articulate that there is more than a mere possibility that a causal relationship exists between the defendant's negligence and the injury for which the plain-

tiff seeks damages.

Civil Procedure : Entry of Judgments

Before final judgment, the trial court may revisit issues previously decided when there has been an intervening change in the controlling law or when new evidence has become available.

Evidence : Witnesses : Expert Testimony

The objective of Daubert's gatekeeping requirement is to ensure the reliability and relevancy of expert testimony. It is to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.

COUNSEL:

For MABEL BROWN, PLAINTIFF (86-CV-2229): HAROLD E. KOHN, MARTIN J. D'URSO, KOHN, SAVETT, KLEIN & GRAF, P.C., PHILADELPHIA, PA USA.

For HELEN V. NARCISE, PLAINTIFF (87-CV-1190): LAURI SUSSMAN SIEGEL, ZARWIN & BAUM, P.C., PHILA, PA USA.

For HELEN V. NARCISE, PLAINTIFF (87-CV-1190): JOSEPH C. KOHN, KOHN, SAVETT, KLEIN & GRAF, P.C., PHILADELPHIA, PA USA.

For ANDRE WILLIAMS, SR., PLAINTIFF (87-CV-1258): HAROLD E. KOHN, JOSEPH C. KOHN, JEANNE P. WROBLESKI, KOHN, SAVETT, KLEIN & GRAF, P.C., PHILADELPHIA, PA USA.

For CHARLES W. STANBACK, SUSANNA STANBACH, PLAINTIFFS (87-CV-3227): ARNOLD E. COHEN, KLEHR, HARRISON, HARVEY, BRANZBURG, ELLERS & WEIR, PHILA., PA.

For CHARLES W. STANBACK, SUSANNA STANBACH, PLAINTIFFS (87-CV-3227): CHARLOTTE E. THOMAS, WOLF, BLOCK, SCHORR AND SOLIS-COHEN LLP, PHILADELPHIA, PA USA.

JUDGES:

ROBERT F. KELLY, J.

OPINIONBY:

ROBERT F. KELLY

OPINION:**MEMORANDUM**

R.F. KELLY, J.

MARCH 7, 2000

Plaintiffs have filed a Motion for Reconsideration of this Court's Order excluding the testimony of Drs. Jannette Sherman and Ian C.T. Nisbet. Plaintiffs initially filed this action alleging that they have suffered from a variety of severe and unusual illnesses as a result of their exposure to polychlorinated biphenyls ("PCBs"), used in the transformers of train cars which these Plaintiffs serviced and maintained in the Paoli Railroad Yard. Plaintiffs' present motion is based on the Third Circuit's review of the aforesaid Order in the context of the residents' cases in *In re Paoli R.R. Yard PCB Litigation*, 35 F.3d 717 (3d Cir. 1994) ("Paoli II"), cert. denied sub nom., 513 U.S. 1190 (1995). Because no final order of judgment had been entered in the worker cases, the Third Circuit did not specifically review this Court's decision [*2] to preclude the opinions of Drs. Sherman and Nisbet with respect to these Plaintiffs. However, according to Plaintiffs, Paoli II is readily applicable to the worker cases and compels that the exclusion of all testimony by Drs. Sherman and Nisbet be reconsidered and reversed. For the following reasons, Plaintiffs' motion is granted in part and denied in part.

I. STANDARD

"The United States Court of Appeals for the Third Circuit has held that 'the purpose of a motion of reconsideration is to correct manifest errors of law or fact or to present newly discovered evidence.'" *Cohen v. Austin*, 869 F. Supp. 320, 321 (E.D. Pa. 1994) (citing *Harsco Corp. v. Zlotnicki*, 779 F.2d 906, 909 (3d Cir. 1985), cert. denied, 476 U.S. 1171, 90 L. Ed. 2d 982, 106 S. Ct. 2895 (1986)). Accordingly, a district court will grant a party's motion for reconsideration in any of three situations: (1) the availability of new evidence not previously available, (2) an intervening change in controlling law, or (3) the need to correct a clear error of law or to prevent manifest injustice. *Dodge v. Susquehanna Univ.*, 796 F. Supp. 829, 830 (M.D. Pa. 1992). [*3] In this case, Plaintiffs contend that reconsideration is warranted to correct a clear error of law and to prevent manifest injustice.

II. PENNSYLVANIA COMMON LAW STANDARD OF CAUSATION

Plaintiffs examine the admissibility of Dr. Sherman's testimony in light of both the Pennsylvania common law standard of causation and the Federal Employers' Liability Act ("FELA"), 45 U.S.C. § 51, standard of causation. Plaintiffs first state that, under Pennsylvania common law, they "need only demonstrate that exposure to a toxic chemical was a 'substantial factor' in causing their illness." Pls.' Mem. at 9. Thus, Plaintiffs argue that "an expert is not required to 'disprove or discredit[] every possible cause other than the one espoused by him,'" id. (citing Paoli

II at 760 n.32), and that "it is enough that reasonable minds are able to conclude that the preponderance of the evidence shows defendant's conduct to have been a substantial cause of the harm to plaintiff." Id. at 10 (citing Paoli II at 760 n.31).

Plaintiffs are not completely accurate. In this regard, the Third Circuit specifically stated: "We do not think that the 'substantial factor' [*4] standard lowers the burden of admissibility here." *Paoli II*, 35 F.3d at 760 n.31. The Third Circuit further noted that:

If plaintiffs' experts failed to rule out alternative causes, it means that these alternative causes may have been the sole causes of plaintiffs' injuries — PCBs may not have played any role at all and certainly may not have been sufficient to bring about the plaintiffs' injuries. Testimony that PCBs increased the risk that plaintiffs would contract the injuries that they contracted does not show that PCBs were a substantial factor in those injuries. Moreover, testimony that plaintiffs' exposure to PCBs makes it likely that PCBs were a substantial factor in plaintiffs' injuries cannot reliably establish that PCBs were in fact a substantial factor unless the expert thought about the possibility that other potential causes of those injuries were in fact the sole cause of those injuries. Even under the substantial factor test, plaintiffs must prove that defendants' actions were a cause of plaintiffs' injuries before the burden switches to defendant to show that the injuries would have occurred even absent any action by the defendant. [*5]

Id. Thus, "if the medical expert's 'opinion on causation has a factual basis and supporting scientific theory' that is reliable, it should be admitted." *Heller v. Shaw Indus., Inc.*, 167 F.3d 146, 157 (3d Cir. 1999) (citing *Kannankeril v. Terminix Int'l, Inc.*, 128 F.3d 802, 809 (3d Cir. 1997)). However, "'where a defendant points to a plausible alternative cause and the doctor offers no explanation for why he or she has concluded that was not the sole cause, that doctor's methodology is unreliable.'" *Heller*, 167 F.3d at 156 (citing *Paoli II*, 35 F.3d at 759 n.27).

III. FELA CAUSATION STANDARD

Plaintiffs next state that the FELA causation standard permits a finding of liability if a defendant's actions "played any part, even the slightest, in producing the [plaintiffs'] injury." Pls.' Mem. at 10 (citing *Rogers v. Missouri P.R. Co.*, 352 U.S. 500, 507, 1 L. Ed. 2d 493, 77 S. Ct. 443 (1957)). Thus, according to Plaintiffs, expert testimony may not even be required in a FELA case to establish that exposure to a toxic chemical may have actionably contributed to a worker's illness. [*6] Pls.' Mem. at 11 (citing *Ulfik v. Metro-Northern Commuter R.R.*, 77 F.3d 54, 59-60 (2d Cir. 1996); *Harbin v. Burlington N.R.*

Co., 921 F.2d 129, 132 (7th Cir. 1990)).

However, Defendants convincingly argue that the FELA causation standard is irrelevant. Defendants first point out that Plaintiffs' contention "that expert testimony is unnecessary does not mean that it can be admitted even if unreliable." Defs.' Opp'n Mem. at 6. Next, Defendants argue that the two cases cited by Plaintiffs do not justify dispensing with expert testimony in this case. Defendants state that in the plaintiff in the Harbin case did present expert proof of causation and that the Seventh Circuit actually held that the plaintiff did not also need expert proof of the defendant's negligence. As for Ulfik, Defendants argue that the particular causal relationship alleged there (dizziness, headache, and nausea after exposure to paint fumes) was held to be a "non-technical matter" by the court and could be decided by a jury without expert testimony. Furthermore, Defendants submit that the Third Circuit has already recognized that the alleged causal connection between PCBs and [*7] human illness is sufficiently esoteric to require expert testimony. *Paoli II*, 35 F.3d at 767-70 (upholding summary judgment against plaintiffs who presented no admissible expert proof of causation). Moreover, Defendants correctly assert that "the FELA causation standard does not make that subject any less esoteric." Defs.' Opp'n Mem. at 7 (citing *Claar v. Burlington N.R.R.*, 29 F.3d 499, 504 (9th Cir. 1994)); see also *Moody v. Maine Cent. R. Co.*, 823 F.2d 693, 695 (1st Cir. 1987) (if drawing a particular conclusion requires specialized knowledge, expert testimony is required) (citing W.P. Keeton, *The Law of Torts* 269 (5th ed. 1984)). Thus, this Court concludes that, like the "substantial factor" standard, the FELA causation standard does not lower the burden of admissibility here.

IV. ADMISSIBILITY OF DR. SHERMAN'S BODILY INJURY OPINIONS

In reviewing the reliability of a physician's testimony the Third Circuit has stated the following:

1. "Performance of physical examinations, taking of medical histories, and employment of reliable laboratory tests all provide significant evidence of a reliable differential diagnosis, [*8] and ... their absence makes it much less likely that a differential diagnosis is reliable." *Paoli II*, 35 F.3d at 758;

2. "Sometimes differential diagnosis can be reliable with less than full information" *Id.* at 759;

3. "[A] physician who evaluates a patient in preparation for litigation should seek more than a patient's self-report of symptoms or illness and hence should either examine the patient or review the patient's medical records simply in order to determine that a patient is ill and what illness the patient has contracted." *Id.* at 762;

4. "Evaluation of the patient's medical records, like performance of a physical examination, is a reliable method of concluding that a patient is ill even in the absence of a physical examination. ... Generally, a doctor only needs one reliable source of information showing that the plaintiff is ill and either a physical examination or medical records will suffice — but the doctor does need at least one of these sources." *Id.*; and

5. "Where [physicians] engaged in few of the standard procedures of differential diagnosis, they had to offer a good explanation as to why [*9] their conclusion remained reliable. Where they did employ such standard techniques, they still had to offer such an explanation if the defendants pointed to some likely cause of the plaintiff's illness other than the defendants' actions." *Id.*

Based on the above, the Third Circuit set forth the following guidelines for reviewing Dr. Sherman's testimony:

Where Dr. Sherman ... offered an opinion as to the source of a party's illness, the district court abused its discretion in excluding that opinion under Rule 702 unless either (1) Dr. Sherman ... engaged in very few standard diagnostic techniques by which doctors normally rule out alternative causes and the doctor offered no good explanation as to why ... her conclusion remained reliable, or (2) the defendants pointed to some likely cause of the plaintiff's illness other than the defendants' actions and Dr. Sherman ... offered no reasonable explanation as to why ... she still believed that the defendants' actions were a substantial factor in bringing about that illness.

Id. at 760. Thus, the Third Circuit concluded that "the opinion of a doctor who has engaged in few standard diagnostic [*10] techniques should be excluded unless the doctor offers a good justification for his or her conclusion" *Paoli II*, 35 F.3d at 761.

Here, Plaintiffs argue that Dr. Sherman evaluated all three worker plaintiffs' medical histories, completed a physical examination of the only surviving worker, studied the literature, and considered alternative causes before reaching her opinions. In addition, Plaintiffs argue that Dr. Sherman considered and rejected several non-PCB causes for Plaintiffs' injuries about which the Defendants questioned her. However, "Paoli II makes clear that Rule 702 requires Dr. Sherman to explain on a plaintiff-by-plaintiff, disease-by-disease basis why her opinion is reliable and why she ruled out alternative causes." Defs.' Opp'n Mem. at 8; see also *Paoli II*, 35 F.3d at 764 (concluding that the exclusion of Dr. Sherman's testimony will not be upheld without examining her testimony concerning particular plaintiffs). Specifically, the Third Circuit stated:

Applying the Daubert analysis ... , unless Dr. Sherman

presented a good explanation for why she could reasonably testify that the illnesses of the plaintiffs [*11] whom she did not examine were caused by PCBs, the district court was within its discretion in excluding Dr. Sherman's testimony. With respect to those plaintiffs whom Dr. Sherman did examine, we conclude that she employed a sufficient number of standard diagnostic techniques that the district court should have presumed that her testimony was reliable. Thus, Dr. Sherman's testimony is admissible with respect to these plaintiffs unless the defendants pointed to particular potential alternative causes and she was unable to explain why she thought these alternatives had not caused the plaintiffs' illnesses.

Paoli II, 35 F.3d at 764-65. Next, this Court will apply the above analysis to Dr. Sherman's opinions regarding the Plaintiffs in the instant actions.

V. DR. SHERMAN'S OPINIONS REGARDING THE WORKERS' PERSONAL INJURIES

A. John Narcise

According to Dr. Sherman, Mr. Narcise had (1) cancer, (2) chronic obstructive pulmonary disease, (3) diabetes, and (4) pancytopenia. In her deposition, Dr. Sherman stated that those conditions "are reflective of those adverse effects that have been shown in animals and other human beings following [*12] exposure to components found in dielectric fluids" (Sherman Dep., dated 5/20/92, at 370-71.) However, as Defendants point out, Dr. Sherman did not examine Mr. Narcise, take a history of him, or perform any laboratory tests on him, but, instead, bases her opinions solely on a review of Mr. Narcise's medical records. Thus, as stated above, unless Dr. Sherman presented a good explanation for why she could reasonably testify that the illnesses of Mr. Narcise were caused by PCBs, this Court was within its discretion in excluding Dr. Sherman's testimony. *Paoli II*, 35 F.3d at 764-65.

In this regard, Defendants argue that nowhere does Dr. Sherman address herself to Mr. Narcise's particular case and explain how or why she determined that cigarette smoking was not the **sole** cause of his cancer or Chronic Obstructive Pulmonary Disease ("COPD"). (Sherman Dep., dated 5/20/92, at 376-78, 383-85.) Similarly, Defendants argue that Dr. Sherman has made no attempt to explain how or why she ruled out obesity or other factors besides PCBs as possible causes of Mr. Narcise's diabetes. As for Mr. Narcise's pancytopenia, the depression of all blood counts, Defendants argue [*13] that Dr. Cassileth noted that such a condition was most likely a side-effect of Mr. Narcise's anti-convulsant medication which he was given to control seizures related to his brain tumor.

In response, Plaintiffs argue that whether Dr. Sherman

accurately rejected smoking as the primary cause of Mr. Narcise's brain tumor is a question of fact for the jury. Pls.' Recons. Mot. at 13 (citing *Paoli II*, 35 F.3d at 746 ("Daubert requires the judge's admissibility decision to focus not on the expert's conclusions but on his or her principles and methodology.")). In addition, Plaintiffs argue that Defendants' contention that Dr. Sherman failed to consider alternative causes to Mr. Narcise's other health problems has no merit because: (1) the FELA standard of causation only requires PCBs to play the slightest role in contributing to their illnesses, (2) the "substantial factor" standard of causation does not require the expert's opinion to disprove or discredit every possible cause other than the one espoused by her, (3) Dr. Sherman was required to review the plaintiff's medical records, not defendant's commentary on such records, and (4) Dr. Sherman considered alternative [*14] causes for Mr. Narcise's illnesses.

Again, Plaintiffs are inaccurate. As already stated above, both the FELA and "substantial factor" standards of causation fail to lower the burden of admissibility here. Indeed, Dr. Sherman's consideration of alternative causes for Mr. Narcise's illnesses does not in and of itself make her opinion reliable where "the defendants pointed to some likely cause of the plaintiff's illness other than the defendants' actions and Dr. Sherman ... offered no reasonable explanation as to why ... she still believed that the defendants' actions were a substantial factor in bringing about that illness." *Paoli II* at 760. Thus, Dr. Sherman's review of Mr. Narcise's medical records does not excuse Plaintiffs' expert from explaining why obesity was not the sole cause of Mr. Narcise's diabetes, nor why smoking was not the sole cause of Mr. Narcise's cancer or COPD.

B. Charles Stanbach

With respect to Charles Stanbach, who died from a tumor located at the junction of his stomach and esophagus, Dr. Sherman opines that Mr. Stanbach's exposure to PCBs was a significant contributing factor in causing his stomach cancer. (Sherman Dep., dated 5/20/92, at [*15] 388.) As with Mr. Narcise, Dr. Sherman bases her opinion solely on her evaluation of Mr. Stanbach's medical records. Therefore, unless Dr. Sherman presented a good explanation for why she could reasonably testify that the illnesses of Mr. Stanbach were caused by PCBs, this court was within its discretion in excluding Dr. Sherman's testimony. *Paoli II* at 764-65.

Here, Defendants point out that, after examining Mr. Stanbach's medical records, Dr. Cassileth observed that the cancer from which Stanbach suffered "is not an uncommon tumor. There are known epidemiological associations with this kind of cancer, including alcohol ingestion, cigarette smoking, and iron deficiency." (Cassileth Report at 8.) While the parties do not dispute that Dr.

Sherman did offer an explanation for why she does not believe smoking caused Mr. Stanbach's cancer, see Paoli II at 764 ("She specifically considered Charles Stanbach's smoking as a possible cause of his esophageal cancer before ruling it out based on when he had stopped smoking and the types of changes he had in his cells."), Defendants argue that Dr. Sherman provides no explanation as to why she rules out other possible causes. Defendants [*16] further argue that Dr. Sherman never ascertained Mr. Stanbach's drinking or dietary history. (Sherman Dep., dated 6/19/92, at 1014.) Moreover, Defendants assert that Dr. Sherman has little, if any, expertise in the subject of gastro-esophageal cancer. *Paoli II*, 35 F.3d at 765 ("In analyzing the adequacy of Dr. Sherman's explanations, we will weigh in the balance Dr. Sherman's somewhat dubious expertise — a factor we have deemed important under the Supreme Court's flexible Daubert inquiry."); see also Sherman Dep., dated 5/20/92, at 389-90, 400-01. Based on the above, this Court's conclusion that Dr. Sherman's opinion is unreliable and inadmissible under Rule 702 remains unchanged.

C. Andre Williams

At her deposition, "Dr. Sherman testified that exposure to PCBs caused plaintiff Andre Williams to develop (1) 'lesions over his back which ... looked very much like chloracne lesions'; and (2) 'polychondritis affecting his eyes, his ears [and] his heart.'" Defs.' Supp. Mem. Regarding Exclusion of the Opinions of Janette Sherman, M.D. at 15 (citing Sherman Dep. at 477). However, unlike Narcise and Stanbach, Dr. Sherman did examine and take a history [*17] from Mr. Williams. Thus, Dr. Sherman's testimony is admissible with respect to Mr. Williams unless the defendants pointed to particular potential alternative causes and she was unable to explain why she thought these alternatives had not caused the plaintiffs' illnesses.

Defendants first argue that Dr. Sherman's opinion that PCB-related chloracne is a "possible" diagnosis is on its face too speculative to qualify as "scientific knowledge" under Rule 702. Defendants cite *Paoli II*, 35 F.3d at 760 n.29, where "the Third Circuit recognized that 'there may ... be circumstances in which a doctor conducts a physical examination but this is insufficient to create a reliable differential diagnosis in the absence of the additional data' that testing procedures would provide." Defs.' Supp. Mem. at 16. Thus, Defendants argue that, "without performing a biopsy, her opinion is at best 'only a hypothesis which [she has] yet to attempt to verify or disprove by subjecting it to the rigors of scientific testing.'" Defs.' Supp. Mem. at 16 (quoting *Paoli II*, 35 F.3d at 764); see also *Mayhew v. Bell S.S. Co.*, 917 F.2d 961, 963 (6th Cir. 1990) (holding [*18] that even under FELA, to render an admissible opinion, "a medical expert must be able

to articulate that there is more than a mere possibility that a causal relationship exists between the defendant's negligence and the injury for which the plaintiff seeks damages.").

Next, Defendants argue that Dr. Sherman's opinion is inadmissible on the alternative grounds that she failed to explain why she ruled out eczematoid dermatitis as a possible sole cause of the skin lesions she noted on Mr. Williams, as Dr. Phillips, a Professor of Medicine at the University of Pennsylvania School of Medicine in the Allergy and Immunology Section, reported. In addition, the Third Circuit noted, "Dr. Sherman admitted she was not an expert in dermatology, and she demonstrated little knowledge about chloracne." 35 F.3d at 767.

Likewise, with respect to Mr. Williams' polychondritis, Dr. Sherman has not provided any explanation as to why she believes Mr. Williams' condition is caused by PCBs and not medications. (Sherman Dep., dated 5/20/92, at 478-80.) According to Defendants, the only data Dr. Sherman cites to support her opinion are the immunological testing results from Antibody Assay Laboratories, [*19] see id. at 490-94, which this Court (affirmed by the Third Circuit) has held to be inadmissible and unreliable as a basis for expert opinion. See *Paoli II*, 35 F.3d at 754.

In response, Plaintiffs argue that the admissibility of Dr. Sherman's opinion does not depend upon her "disproving or discrediting" every speculative cause articulated by a defense witness. See id. at 761 n.32. However, the Third Circuit, in *Paoli II*, held that "if plaintiff's experts failed to rule out alternative causes, it means that these alternative causes may have been the sole causes of plaintiff's injuries — PCBs may not have played any role at all and certainly may not have been sufficient to bring about the plaintiffs' injuries." Id. at 760 n.31. Thus, Dr. Sherman's opinion on causation should remain excluded because she failed to rule out alternative causes. Id. at 760.

VI. DR. SHERMAN'S MEDICAL MONITORING OPINIONS

On October 20, 1995, this Court denied Defendants' Motion *In Limine* to Exclude the Medical Monitoring Opinion Testimony of Dr. Sherman at the related trial of the residential plaintiffs. With serious [*20] misgivings about the admissibility of such testimony, this Court determined that the most expeditious and practical way of handling the matter was for the case to go to trial and leave the jury to decide the value of Dr. Sherman's testimony, especially in light of the unique history of this case. Now, with the added experience of the residential trial, along with the opportunity to reflect on the applicable law, this Court will revisit the arguments made by the parties in order to decide the present motion. n1

n1 Defendants remind this Court that there has been no final judgment as to Mr. Williams' case, nor was his case before the Court of Appeals in Paoli II. Furthermore, Defendants submit that this Court is free to revisit its opinion excluding Dr. Sherman's medical monitoring opinion to base the exclusion of that opinion on grounds different from those that supported the 1992 exclusion Order. *NL Indus., Inc. v. Commercial Union Ins. Co.*, 65 F.3d 314, 324 n.8 (3d Cir. 1995) (before final judgment, trial court may revisit issues previously decided "when there has been an intervening change in the controlling law [or] when new evidence has become available").

[*21]

Andre Williams is the only living worker plaintiff; therefore, he is the only FELA plaintiff pursuing a claim for medical monitoring. Here, Plaintiffs contend that the Third Circuit's finding that Dr. Sherman's medical monitoring "passes Daubert muster" along with this Court's recent denial of a related motion *in limine* warrant reconsideration of this Court's earlier ruling with respect to Mr. William's case. However, in Paoli II, the court observed that Dr. Sherman's methodology in formulating her monitoring opinion was very much open to Rule 702 challenge. Thus, the substance of Plaintiffs' experts' medical monitoring program had not been addressed by Defendants in prior proceedings. See *Paoli II*, 35 F.3d at 789 ("It may be true that failure to analyze the specificity or sensitivity of a particular test sometimes constitutes a methodological flaw that renders a doctor's opinion that that test is a useful diagnostic technique unreliable and hence inadmissible. But the defendants fail to point to evidence in the record suggesting that an analysis of specificity and sensitivity is necessary"). Defendants now do make those arguments as to Dr. Sherman's [*22] monitoring opinion for Mr. Williams and, as set forth below, have provided a record that amply supports the exclusion of that opinion. Defs.' Supp. Mem. at 22.

The purpose for medical monitoring or screening is early detection and treatment of disease. However, monitoring should not be conducted if early detection and the prospect for successful treatment are not available for the disease. (Guzelian Decl. at P 6.) This risk/benefit approach is consistent with one of the fundamental principles of medical science — "Above all, do no harm." (Herzstein Decl. at P 4.)

As Defendants' experts, Dr. Guzelian and Dr. Herzstein, point out, the medical monitoring process itself entails substantial health risks. Not only do the testing procedures themselves have the potential to cause significant injuries, but a positive result triggers an increasingly

invasive series of medical procedures which are necessary to confirm the initial result. n2 In addition, there are emotional risks to a patient's health — a false test result will either provide false reassurance to the patient of the absence of a disease or, in the alternative, cause great anxiety and behavioral changes that often accompany [*23] a patient labeled with a disease. (Herzstein Decl. at P 4.)

n2 In those cases in which the positive result turns out to be a "false positive" — that is, the condition indicated by the test was not actually present — the resulting cascade of medical intervention is totally unnecessary and potentially harmful. (Herzstein Decl. P 4.) According to Drs. Guzelian and Herzstein, reliable medical methodology is designed to minimize the possibility of such errors — false test results and the resulting harms to the patient — in the screening process.

Thus, like any medical intervention, the physician must first establish that the probable usefulness of those tests outweighs the attendant risks prior to subjecting a healthy person to screening tests. n3 Such a risk/benefit analysis determines whether a screening test for an asymptomatic patient is justified. (Guzelian Decl. at P 7.) This analysis requires : (1) determining whether a screening test is capable of detecting the disease in question (the "target condition") [*24] early enough to improve the patient's clinical outcome (Guzelian Decl. P 6; Herzstein Decl. PP 5–6), (2) determining whether the test is sufficiently accurate, measured by its sensitivity and specificity, to be a useful means of looking for the target disease, taking into account the test's accuracy and predictive power, (Guzelian Decl. P 8; Herzstein Decl. PP 5, 7), and (3) determining the likelihood that the test under consideration will find what she is looking for in the person or group being screened (Guzelian Decl. PP 9–11; Herzstein Decl. PP 5, 8). In addition, the physician must consider the individual patient's health status before prescribing screening tests for a perceived risk of future disease. (Herzstein Decl. at P 9.)

n3 "The methodology for making this determination has now been set forth in a number of widely recognized and authoritative sources, including the Report of the U.S. Preventive Services Task Force, Guide to Clinical Preventive Services (1989) and the criteria issued by the U.S. Agency for Toxic Substances and Disease Registry (ATSDR) to determine the propriety of medical monitoring under CERCLA." Defs.' Mot. *In Limine* to Exclude Dr. Sherman's Medical Monitoring Opinion, filed October 2, 1995 before the related residential trial, at 9.

[*25]

Defendants point to several deficiencies in Dr. Sherman's methodology in formulating her opinion that an extensive battery of periodic screening tests is required. n4 Such deficiencies include the following:

1. Dr. Sherman proposes tests that have no known medical benefit in the treatment of any condition and there is no recognized medical purpose in performing such tests on asymptomatic persons. (Guzelian Dec. at P 14; Herzstein Dec. at P 12);

2. Dr. Sherman has not considered or analyzed the accuracy of the tests. In this regard, she has failed to appreciate or apply in substance the concepts of "sensitivity" and "specificity." Thus, she failed to determine whether any of the components of her protocol are likely to be accurate in detecting the conditions she believes may be caused by Plaintiff's exposure. (Guzelian Dec. at P 14; Herzstein Dec. at P 13); and

3. Dr. Sherman has not considered the prevalence of the target diseases. This renders her methodology unreliable, since she is without the capability of comparing the risks and benefits of monitoring in the manner that any reliable medical methodology requires. (Guzelian Dec. at P 14; Herzstein Dec. at P 13.)

n4 Aside from Dr. Sherman's lack of scientific methodology is Defendants' contention that Dr. Sherman's medical monitoring opinion relies on a factual assumption that Plaintiffs were exposed to dioxins and furans, as well as PCBs. Because this Court already determined that all testimony, evidence, and statements to the jury concerning dioxins and furans and the alleged health effects of those substances should be excluded, Defendants convincingly argue that Dr. Sherman's opinion does not "fit" the issues to be tried, since Plaintiffs will be unable to prove at trial that they were in fact exposed to the substances to which Dr. Sherman assumed they had been exposed. See *Joiner v. General Elec. Co.*, 864 F. Supp. 1310 (N.D. Ga. 1994), rev'd, 78 F.3d 524 (11th Cir. 1996), rev'd, 522 U.S. 136, 139 L. Ed. 2d 508, 118 S. Ct. 512 (1997).

[*26]

Furthermore, the applicable reliability factors of a Rule 702 analysis point strongly to the inadmissibility of Dr. Sherman's monitoring opinion. For example, as stated above, by prescribing numerous screening tests without considering the information that is critical to an assessment of their necessity, Dr. Sherman's approach creates a great potential for error in the screening process. In addition, Dr. Sherman's medical monitoring approach is sci-

entifically unsound and not accepted by the medical community. Finally, Dr. Sherman's "somewhat dubious expertise," Paoli II at 765, when viewed in conjunction with the fundamental methodological flaws discussed above, favors ruling her monitoring opinion inadmissible under Rule 702. n5

n5 Another independent basis for excluding Dr. Sherman's medical monitoring opinion is that Plaintiffs may recover only for special monitoring tests made necessary by their alleged exposure to PCBs; however, many of the tests in Dr. Sherman's monitoring protocol are procedures that she would recommend for any person, regardless of alleged chemical exposure. Other tests Dr. Sherman would prescribe only if a plaintiff develops certain symptoms in the future, but she cannot say that it is probable that any plaintiff in fact will ever develop such symptoms.

[*27]

In Paoli II, the Third Circuit Court of Appeals held that this Court "abused its discretion in relying purely on Dr. Sherman's failure to understand certain terms in excluding her testimony on medical monitoring as unreliable." *Paoli II*, 35 F.3d at 790. However, Defendants have now pointed to evidence in the record that shows an analysis of specificity and sensitivity is necessary before concluding that particular screening tests are needed. See *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 119 S. Ct. 1167, 1176, 143 L. Ed. 2d 238 (1999) ("The objective of [Daubert's gatekeeping] requirement is to ensure the reliability and relevancy of expert testimony. It is to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field."). In addition, Defendants have shown, inter alia, how Dr. Sherman has "failed to analyze specificity and sensitivity in substance." *Paoli II*, 35 F.3d at 790. Based on the above, this Court will deny Plaintiffs' motion with respect [*28] to Dr. Sherman's medical monitoring opinion.

VII. DR. NISBET'S OPINION

The parties, for the most part, do not dispute that Dr. Nisbet's opinions in the worker cases do not materially differ from his opinions in the residential cases and that the Third Circuit's reversal of the exclusion of the vast majority of his testimony in the residential cases compel that he be permitted to testify, subject to the same parameters, in the workers' cases. See *Paoli II*, 35 F.3d at 774, 779. Here, it is appropriate for this Court to reconsider its Order excluding Dr. Nisbet's opinion in these cases to conform to the holdings of Paoli II. Thus, only

Dr. Nisbet's opinions as to his "recalculation of AML lab tests and ... his back calculations based on the Eco Logic data" remain inadmissible. *Id. at 778*.

Based on the above, Plaintiffs' Motion for Reconsideration of this Court's 1992 Order excluding the testimony of Drs. Sherman and Nisbet in these cases is granted in part and denied in part. An appropriate Order will follow.

ORDER

AND NOW, this 7th day of March, 2000, upon consideration of Plaintiffs' Motion for Reconsideration of [*29] this Court's 1992 Order excluding the testimony of Drs. Sherman and Nisbet in the above-captioned matter, and all responses thereto, it is hereby ORDERED that:

1. Plaintiffs' Motion for Reconsideration regarding Dr. Sherman's personal injury opinions is DENIED;

2. Plaintiffs' Motion for Reconsideration regarding Dr. Sherman's medical monitoring opinion is DENIED; and

3. Plaintiffs' Motion for Reconsideration regarding Dr. Nisbet's expert testimony is GRANTED with respect to the vast majority of Dr. Nisbet's expert testimony and DENIED only as to his recalculation of American Medical Laboratory (AML) tests and his back calculations based on the Eco Logic data.

BY THE COURT:

ROBERT F. KELLY, J.

TAB 7

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DAVID ROBINSON, Plaintiff, v. DONALD VAUGHN, Defendant.**CIVIL ACTION NO. 91-7646****UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF
PENNSYLVANIA***1992 U.S. Dist. LEXIS 19518***December 2, 1992, Decided****December 2, 1992, Filed****COUNSEL:**

For DAVID ROBINSON, PLAINTIFF: TERI B. HIMEBAUGH, ANTHONY C. BRUNEIO, 212 WENDOVER STREET, PHILA, PA 19128, USA.

For DONALD VAUGHN, WARDEN, DEFENDANT: DENISE A. KUHN, OFFICE OF ATTORNEY GENERAL, 21 S. 12TH ST., 3RD FL., PHILA, PA 19107-3603, USA.

JUDGES:

[*1] BECHTLE

OPINIONBY:

LOUIS C. BECHTLE

OPINION:**MEMORANDUM AND ORDER**

BECHTLE, CH.J.

Presently before the court is defendant's motion for summary judgment. For the reasons set forth below, defendant's motion will be granted.

I. BACKGROUND

Plaintiff David Robinson ("Robinson"), an inmate at the State Correctional Institute at Graterford ("Graterford"), brought this action pursuant to 42 U.S.C. § 1983 against Donald Vaughn, the Superintendent at Graterford ("Superintendent Vaughn"), alleging that his Fourth, Eighth and Fourteenth Amendment rights under the United States Constitution were violated because, as an electrician on a prison work crew, he was exposed to asbestos. Robinson has not alleged that, as a result of his alleged exposure to asbestos, he has contracted an asbestos-related disease. Instead, Robinson alleges that Superintendent Vaughn knew or should have known about the presence of asbestos inside Graterford, that Superintendent Vaughn failed to warn him of the risks

of exposure to asbestos, and that Superintendent Vaughn failed to take precautions or other measures to insure Robinson's health and safety. In addition, Robinson alleges that Superintendent [*2] Vaughn's conduct constitutes deliberate indifference to his health and safety in violation of the Eighth Amendment prohibition against cruel and unusual punishment.

Superintendent Vaughn denies Robinson's allegations and moves for summary judgment. Superintendent Vaughn argues that as soon as he became aware of friable asbestos in certain areas of the prison, these areas were closed and all inmates and staff were forbidden access until abatement and encapsulation procedures had been completed. As a result, Superintendent Vaughn argues that he never deliberately exposed Robinson, nor any other inmate, to asbestos. Finally, Superintendent Vaughn argues that this court lacks jurisdiction over this matter because Robinson has not stated an "injury in fact" under Article III of the Constitution.

II. STANDARD FOR SUMMARY JUDGMENT

Summary judgment shall be granted "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). Whether a fact is material will be determined [*3] by reference to the "substantive evidentiary standards that apply to the case." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). Whether a genuine issue of material fact is presented will be determined by asking if "a reasonable jury could return a verdict for the non-moving party." *Id.*

On a motion for summary judgment, the non-moving party has the burden to produce evidence to establish prima facie each element of its claim. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986). Such evidence and all justifiable inferences that can be drawn from it are to be

taken as true. *Anderson*, 477 U.S. at 255. However, if the non-moving party fails to establish an essential element of its claim, the moving party is entitled to a judgment dismissing that claim as a matter of law. *Celotex*, 477 U.S. at 322-23.

III. DISCUSSION

As a preliminary matter, to establish a case or controversy under Article III of the Constitution, a litigant first must clearly demonstrate that he has suffered an "injury in fact." *Whitmore v. Arkansas*, 495 U.S. 149 (1990). [*4] That injury must be "concrete in both a qualitative and temporal sense." *Whitmore*, 495 U.S. at 155. In other words, the plaintiff must allege an injury to himself that is "distinct and palpable," as opposed to merely "abstract," and the alleged harm must be actual or imminent, not "conjectural" or "hypothetical." *Id.* (citations omitted). If a litigant fails to clearly and specifically set forth facts sufficient to satisfy these Art. III standing requirements, "a federal court is powerless to create its own jurisdiction by embellishing otherwise deficient allegations of standing." *Id.* at 155-56 (citations omitted).

In this case, Robinson alleges that his constitutional rights were violated because of his alleged exposure to asbestos, and that because of his alleged exposure, he lives in constant fear of contracting an asbestos-related disease. However, under Pennsylvania law, mere exposure to asbestos, absent some manifestation of an asbestos-related disease, does not give rise to a cause of action. See *Marinari v. Asbestos Corp.*, 612 A.2d 1021, 1028 (Pa. Super. 1992) ("injury is done when [*5] the act heralding a possible tort inflicts a damage which is physically objective and ascertainable" (citations omitted)). Moreover, courts in this District have consistently held that mere exposure to asbestos in prison, and a prison official's failure to warn about the presence of asbestos, is insufficient as a matter of law to establish a constitutional deprivation. See *Alim v. Vaughn*, 1992 U.S. Dist LEXIS 12503 (E.D. Pa. 1992); *Hannibal v. Lyons*, 1990 U.S. Dist LEXIS 8261 (E.D. Pa. 1990); *Gonzalez v. Lyons*, 1989 U.S. Dist. LEXIS 6812 (E.D. Pa. 1989). Also, Robinson's fear of contracting an illness related to his exposure to asbestos

is too speculative to give rise to a cause of action. See *Seymour/Jones v. Bricker*, 1990 U.S. Dist. LEXIS 17405 (E.D. Pa. 1990). Consequently, Robinson's claim must fail because he has not established that he has suffered an "injury in fact," and this court "is powerless to create its own jurisdiction by embellishing deficient allegations of standing." See *Whitmore*, supra.

As for Robinson's claim that Superintendent Vaughn [*6] acted with deliberate indifference to his health and safety, to succeed on this claim, Robinson must show that Superintendent Vaughn acted with a culpable state of mind. *Wilson v. Seiter*, 111 S.Ct. 2321 (1991). However, there is no evidence that Superintendent Vaughn intentionally exposed Robinson to asbestos, nor is there any evidence that Superintendent Vaughn ignored the presence of friable asbestos once he became aware of it. To the contrary, the evidence shows that as soon as Superintendent Vaughn became aware of friable asbestos in certain areas of the prison, these areas were closed and all inmates and staff were forbidden access until abatement and encapsulation procedures had been completed. Thus, Robinson has failed to establish an essential element of his claim, that Superintendent Vaughn acted with deliberate indifference, and, therefore, Superintendent Vaughn is entitled to a judgment dismissing this claim as a matter of law. *Celotex*, 477 U.S. at 322-23.

IV. CONCLUSION

For the reasons set forth above, Vaughn's motion for summary judgment will be granted. Judgment will be entered in favor of Vaughn [*7] and against Robinson.

An appropriate Order will be entered.

ORDER

AND NOW, TO WIT, this 2nd day of December, 1992, upon consideration of defendant Donald Vaughn's motion for summary judgment, and the responses thereto, IT IS ORDERED that said motion is granted. Judgment is hereby entered in favor of defendant Donald Vaughn and against plaintiff David Robinson.

LOUIS C. BECHTLE, CH.J.

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing Appendix of Unpublished Opinions and Orders Cited in Wyeth's Memorandum in Support of Motion to Dismiss the Complaint has been served by first-class mail, postage prepaid, this 14th day of August, 2002, on the following counsel of record:

Scott R. Shepherd, Esquire
James C. Shah, Esquire
Shepherd & Finkelman, LLC
117 Gayley Street
Suite 200
Media, PA 19063

Paul J. Geller, Esquire
Jonathan M. Stein, Esquire
Cauley Geller Bowman & Coates, LLP
2225 Glades Road
Suite 421A
Boca Raton, FL 33431

Steven E. Cauley, Esquire
Curtis L. Bowman, Esquire
Gina M. Cothorn, Esquire
Cauley Geller Bowman & Coates, LLP
11311 Arcade Drive, Suite 200
Little Rock, AR 72212

MICHAEL T. SCOTT